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VC150 Vital Signs Monitor
Operator's Manual

VC150 Vital Signs Monitor
English
KO00065K

Innokas Medical

NOTE

The information in this manual applies to VC150 Vital Signs Monitor. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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1 Introduction

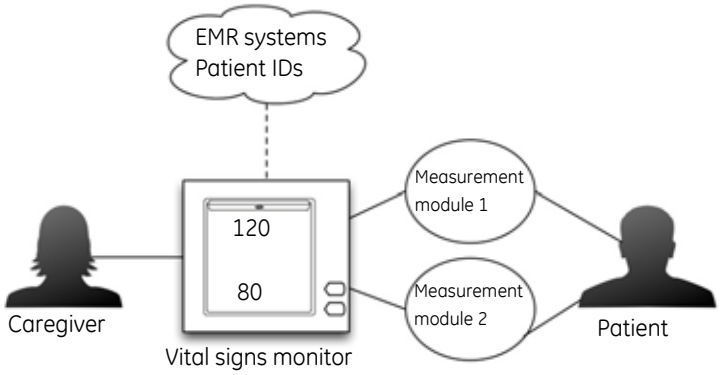
About this device

The VC150 vital signs monitor provides a small, portable monitoring alternative for sub-acute hospital and non-hospital settings. The monitor is for use on adult, pediatric, or neonatal patients—one at a time. The battery-operated monitor offers noninvasive determination of systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP), pulse rate, respiration rate (only available with Nellcor and Masimo technologies), oxygen saturation, and temperature. Monitors are available with or without (excluding NIBP, which is always available) integrated printers as well as the following parameters and technologies.

- NIBP (SuperSTAT or Auscultatory Reference Algorithms), Pulse Rate
- SpO_2: GE TruSignal, Nellcor OxiMax, or Masimo rainbow® SET®
- Temperature: Welch Allyn SureTemp® Plus or Exergen

The model of the VC150 vital signs monitor determines which parameters are available in your monitor. Please refer to applicable sections.

Using the VC150 vital signs monitor, a caregiver can measure, display and record patient vital sign data that is derived from each parameter. The monitor can transfer the patient's electronic medical record to HIS (hospital information system). The monitor is also capable of alerting to changes in the patient's condition or when it is unable to effectively monitor the patient's condition. The monitor also detects alarm limit conditions and gives audible and visual notification of these conditions. All of the main operations of the monitor are only a touch away. Please review the factory default settings and, where applicable, enter settings appropriate for your use. The monitor can use WLAN or Hostcomm to communicate with the EMR (Electronic Medical Record), export PDFs, print patient data with strip printer and use USB or Remote Management to export/import settings, license keys and update software.



Intended use

The VC150 is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.

The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric, and neonatal patients.

The optional GE TruSignal pulse oximetry and accessories are indicated for continuous noninvasive monitoring of functional oxygen saturation (SpO_2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric, and neonatal patients.

The optional Masimo Rainbow SET® Pulse CO-oximetry and accessories are indicated for the continuous noninvasive monitoring of:

- functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric, and neonatal patients,
- carboxyhemoglobin saturation (SpCO) for adult and pediatric patients,
- methemoglobin saturation (SpMet) for adult, pediatric, and neonatal patients,
- total hemoglobin concentration (SpHb) for adult and pediatric patients, and/or
- respiratory rate (RRa) for adult and pediatric patients.

The optional Nellcor™ oximetry and accessories are indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused. The optional Oximax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The optional Nellcor™ Respiration Rate parameter is intended for the continuous, noninvasive monitoring of respiration rate in adult patients who are well perfused during non-motion conditions.

The optional Welch Allyn SureTemp Plus electronic thermometer is intended to measure oral, axillary, and rectal temperature of adult and pediatric patients. The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.

A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver.

The portable device is designed for use in hospitals and hospital-type facilities. The VC150 can also be used in satellite areas or alternate care settings.

"Portable" refers to the ability of the VC150 to be easily moved by the caregiver, such as on a roll stand. The VC150 is not intended to be used for continuous monitoring during patient transport.

CAUTION
This device is not intended for home use. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Additional information on product use

The VC150 vital signs monitor is for use as prescribed by physicians, physician assistants, registered nurses, certified registered nurse anesthetists, or other qualified medical personnel trained in the use of the equipment. Using this monitor, a caregiver can view, record, and recall clinical data derived from each parameter. The user interface has been localized into selected languages whereas the localized manual has more language options available.

The VC150 vital signs monitor is intended to monitor one patient at a time in a clinical setting with a caregiver present.

WARNING
The monitor *is not* intended for use as critical care monitor.

The monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Contraindications

This device is not designed, sold, or intended for use except as indicated.

Dangers, warnings, cautions, and notes

The terms **Danger**, **Warning**, **Caution** and **Note** are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance. Hazard is defined as a source of potential injury to a person.

DANGER indicates a hazardous situation that, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Safety precautions

DANGER

To protect against injury from electric shock, avoid placing the device on surfaces with visible liquid spills. Do not soak or immerse the device in liquids. Always turn off and disconnect the power cord from the AC power supply before cleaning the device. Use cleaning solutions sparingly.

WARNINGS

To ensure patient safety, use only parts and accessories manufactured specified in the VC150 supplies and accessories manual. Parts and accessories used shall meet the requirements of IEC 60601-1.

Disposable devices are intended for single use only. They should not be reused.

To avoid personal injury, do not perform any service work on the monitor unless qualified to do so.

If powering the monitor from an external power adapter or converter, use only an adapter that has been specified for this monitor. Refer to the VC150 supplies and accessories document.

The monitor is not intended for use during transport of a patient outside a professional healthcare facility.

If the monitor is dropped, it must be serviced immediately.

Connect only IEC 60601 compliant, single isolated USB devices intended for patient care.

Carefully route the external AC/DC power converter, air hoses, and all cables to reduce the possibility of entanglement or strangulation.

Do not immerse the monitor in water. If the monitor is splashed with water or becomes wet, wipe it immediately with a dry cloth.

Do not immerse sensors or patient cables in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof).

Examine the power cord periodically. Discontinue use and replace if damaged. Replace the power cord, as necessary, with a regulatory-approved cord for the country of use.

CAUTION: Do not use extension cords or adapters of any type.

Avoid swinging the monitor, or entangling the monitor and its accessories with a mount or roll stand, as this could cause the monitor to drop, leading to patient or user injury and equipment damage.

WARNINGS

The accuracy of the vital sign values may be compromised 1) if you do not hear two beeps when the screen changes from power-up to home or 2) it is difficult to make selections on the touch screen and calibration of the screen does not solve the problem. Contact Innokas Medical technical support in both cases.

Do not perform any testing or maintenance on a sensor while it is being used to monitor a patient.

Verify calibration of the NIBP parameter (temperature and pulse oximeter do not require calibration). Refer to the service manual for instructions.

Keep the monitor and its accessories out of the patient's reach when not in use.

Place the monitor on a rigid, secure surface or use only mounting hardware that has been specified for this monitor. Refer to the VC150 supplies and accessories document.

Only use the monitor in areas where adequate ventilation exists.

Do not cover the ventilation plates at the bottom and the top of the monitor.

Use only a battery type that has been specified for this monitor. Other batteries may not provide the same operating time and may cause unexpected monitor shutdown. Other batteries may be incompatible with the internal charger and may cause battery acid leakage, fire, or explosion. Refer to the VC150 supplies and accessories document.

Caution should be taken to not set alarm limits to extreme values, as this can render the alarm system useless.

Do not modify this equipment without authorization of the manufacturer.

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Periodically, and whenever the integrity of the monitor is in doubt, test all functions.

The performance of the monitor may be degraded if it is operated or stored outside of the environmental conditions specified in this manual.

The monitor meets standards IEC 60601-1 and ISO 9919 for shock and vibration. If the monitor is subjected to conditions exceeding these standards, performance may be degraded.

Do not use the monitor in the presence of magnetic resonance imaging (MRI) devices. There have been reports of sensors causing patient burns when operating in an MRI environment.

WARNINGS

Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.

Do not use in the presence of an oxygen-enriched atmosphere (oxygen tent).

Operating the monitor near equipment which radiates high-energy electromagnetic and radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause false alarm conditions. If this happens, reposition the monitor and temperature probe away from the source of interference and perform a new measurement.

Do not gas sterilize or autoclave the monitor.

The monitor should not be used on patients who are connected to cardiopulmonary bypass machines.

To reduce the risk of electric shock, do not remove the cover or the back. Refer service work to service personnel.

If the accuracy of any determination reading is questionable, first check the patient's vital signs by alternate means and then check the monitor for proper functioning.

This equipment is not intended for use in the presence of electrosurgery/HF (high frequency) electrosurgical equipment.

To prevent cross-contamination, clean exterior surfaces of the monitor, monitor accessories, and reusable sensors on a regular basis in compliance with your institution's infection control unit and/or biomedical department's local policy.

Do not disassemble the monitor as personal injury may result.

The monitor and its accessories are to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read and understood before use.

Use only approved accessories. For a list of approved accessories, refer to the VC150 supplies and accessories document. Substitution of a component different from that supplied might result in measurement error. Other cables and accessories may cause a safety hazard or damage the equipment or system.

The monitor cannot recognize whether a cable is disconnected from the nurse call interface. Do not leave the patient unattended and rely solely on remote alarm. The remote alarm is not intended to replace patient monitoring by trained nurses.

Arrange cables and accessories in such a way that no hazard can occur.

Stop the exam should a hazard develop that may endanger the patient, operator or bystanders.

WARNINGS

While monitoring patients, use only those measurement values that fall within ranges defined in specifications sections of "NIBP specifications" on page 6-17, "GE TruSignal SpO2 specifications" on page 7-14, "Masimo rainbow SET® SpO2 specifications" on page 8-32, "Nellcor SpO2 specifications" on page 9-30, "Welch Allyn temperature specifications" on page 11-11 and "Exergen temperature specifications" on page 12-7.

Unauthorized personnel can view patient records stored in the device. Hospital policies and practices must prevent unauthorized access to the monitor.

CAUTIONS

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Do not place VC150 monitor cables or accessories in any position that might cause them to fall on the patient. Do not lift the monitor or accessories by the patient cables.

Ensure that any hoses or cables between the monitor and the patient are long enough and that patient will not become pinched or pulled on.

Always remove the sensor from the patient and completely disconnect the patient from the sensors before bathing the patient.

Do not place the monitor where the controls can be changed by the patient.

To comply with the exposure requirements for wireless networks (WLAN), the monitor must be operated with a separation distance of 20 cm or more from a person's body.

Do not place the VC150 monitor touch screen against a surface.

Do not place the monitor on electrical equipment that may affect the monitor, preventing it from working properly.

Do not expose the monitor or accessories to excessive moisture such as direct exposure to rain.

Do not place containers containing liquids, gases, or other flammable or humid material on or near the monitor.

Patient Safety - If a sensor or a cable is damaged in any way, discontinue use immediately.

The SpO_2 sensor site must be inspected at least every two (2) hours to ensure adequate adhesion, circulation, skin integrity and correct optical alignment; and if the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.

To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.

CAUTIONS

Do not use damaged sensors or patient cables. Do not use a sensor or a patient cable with exposed optical or electrical components.

Circulation distal to the sensor site should be checked routinely.

Inspect probe covers for contaminants prior to use.

The monitor does not include any user-replaceable fuses. Refer service work to service personnel.

The connection of equipment or transmission networks other than as specified in these instructions can result in electric shock hazard. Alternate connections will require verification of compatibility and conformity to IEC/EN 60601-1-1 by the installer.

Do not connect the monitoring system to an electrical outlet controlled by a wall switch, since this increases the risk of removal of AC power to the monitoring system.

When the monitor's battery has been completely discharged, the monitor must be connected to an external power supply before monitoring can resume.

When the Battery Low (5 minutes left) alarm is signaled, NIBP is disabled and the monitor will automatically shut down in 5 minutes. Connect the power cable to continue using the monitor.

VC150 is not intended for use as an apnea monitor.

NOTES

The monitor must be protected by a network firewall and must not be exposed to the Internet.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

The 5150-5250 MHz frequency band is for indoor use only, to reduce potential for harmful interference to co-channel mobile satellite systems.

NOTE

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer or an experienced WLAN technician for help.

Product compliance

VC150 vital signs monitor

Compliance classifications

The VC150 Vital Signs Monitor is classified in the following categories for compliance with IEC 60601-1:

- Internally powered or Class I when powered from external supply.
- Portable.
- For continuous operation.
- Not suitable for use in the presence of flammable anesthetics.
- Not for use in the presence of an oxygen-enriched atmosphere (oxygen tent).
- Type BF defibrillator-proof applied parts.
- IPX1, degree of protection against ingress of water.
- Sterilization/Disinfection, refer to "Maintenance" on page B-1.
- Software is developed in accordance with IEC 60601-1-4.
- The monitor complies with IEC 60601-2-49.
- The alarm system is developed in accordance with IEC 60601-1-8.
- The VC150 monitor is a Group 1 Class B device: Group 1 contains all ISM (Industrial, scientific and medical) equipment in which there is radio-frequency energy that is intentionally generated and/or conductively coupled and is necessary for the internal functioning of the equipment itself. Class B equipment is equipment suitable for use in all establishments.
- The SpO_2 parameter complies with ISO 9919.
- The NIBP parameter complies with EN/IEC 60601-2-30.
- The temperature parameter complies with ASTM E-1112-00 and EN 12470-5.
- Defibrillation-protected. When used with the recommended accessories, the monitor is protected against the effects of defibrillator discharge. If monitoring is disrupted by the defibrillation, the monitor will recover.

- Biocompatibility. The monitor fulfills biocompatibility requirements only when accessories listed in VC150 supplies and accessories document are used.
- This product conforms with the essential requirements of the Medical Device Directive 93/42/EEC. Accessories without the CE mark are not guaranteed to meet the Essential Requirements of the Medical Device Directive.
- Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1.

Wireless compliance

- This product complies with IEEE 802.11-2007 and 802.11 a/b/g/n protocols for wireless networking. This product also complies with IEEE 802.11e and WMM Quality of Service guidelines.
- This product supports 802.11n Single-Input, Single-Output (SISO) only.

Electromagnetic compatibility (EMC)

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2, Medical Device Directive 93/42/EEC and CISPR 11 (Group 1, Class B) for radiated and conducted emissions. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNINGS

Use of known RF sources, such as cell/portable phones, or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation of this device/system. Consult qualified personnel regarding device/system configuration.

Use only approved accessories. Refer to the VC150 supplies and accessories document. Other cables and accessories may cause a safety hazard, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system or interfere with the measurement.

The monitor may cause radio interference or may disrupt the operation of nearby equipment. Mitigation for such disruption may require re-orienting or relocating the monitoring system or shielding the location.

CAUTIONS

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

EMC — Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Do not undertake any electrical modifications to the monitor that are not obtained from Innokas Medical. Such changes or modifications to the monitor may cause EMC issues with this or other equipment. This device/system is designed and tested to comply with applicable standards and regulations regarding EMC and needs to be installed and put into service according to the EMC information stated as follows: This device/system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Mains power should be that of a typical commercial or hospital environment.

NOTE

Medical electrical equipment requires special electromagnetic compatibility (EMC) precautions which must be considered when installing and putting this equipment into operation. Refer to the service manual for information.

Exergen temporal scanner

The Exergen temporal scanner has these additional classifications:

- Type BF applied part
- Internally powered (battery operated)
- IPX0, degree of protection against ingress of water

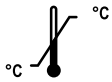
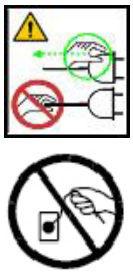
Monitor symbols

NOTE

The model of the monitor determines which symbols appear on it.

	Attention, consult accompanying documents.
	External communications port connector
	On/Off button (the only mechanical button on the monitor)
	Caregiver symbol
	External DC power input
	Defibrillator-proof type BF equipment
	WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.
 2013-11	Manufacturing date: This symbol is accompanied by the date of manufacture.
	Classified with respect to electric shock, fire, and mechanical and other specified hazards only in accordance with CAN/CSA C22.2 No. 601.1 and UL 2601-1 (UL 60601-1). Also evaluated to IEC 60601-2-30.

CE 0598	This product conforms with the essential requirements of the Medical Device Directive 93/42/EEC. Accessories without the CE mark are not guaranteed to meet the Essential Requirements of the Medical Device Directive.
IPX1	This product is protected against vertically falling drops of water and conforms with the IEC 60529 Standard at the level of IPX1. No harmful effects will come of vertically falling drops of water making contact with the monitor.
Rx ONLY U.S.	FDA Prescriptive Device symbol for: "Caution: Federal law restricts this device to sale by or on the order of a physician."
REF	Catalog or orderable part number.
SN	Device serial number.
	Consult instructions for use.
	The unit has a WLAN device inside.
	USB port.
	Atmospheric pressure limitations.
	Fragile. Handle with care.
	Humidity limitations.

	Temperature limitations.
	CAUTION — Safety ground precaution. Remove power cord from the mains source by grasping the plug. ***Do not*** pull on the cable.

Symbols for Exergen temporal scanner

	Attention, consult accompanying documents.
	Type BF Applied Part.
	WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.
 2013-11	Manufacturing date: This symbol is accompanied by the date of manufacture.
IPX0	Ordinary Equipment.
	Measurement **On** button.

About this manual

Printed copies of this manual

The letter shown in this revision history table relates to the release level of this document.

Revision	Comments
KO00065K	Release level of this document.

Printed copy of the manual

A paper copy of this manual will be provided upon request (in the U.S.). Contact distributor of this product and request the English manual.

Conventions used in this manual

Within this manual, abbreviations, special styles and formats are used to refer to concepts, or distinguish among terms viewed on screen, an area you must select, or a list of menu commands you must select. Examples:

- For technical documentation purposes, the abbreviation GE is used for the legal entity name, GE Medical Systems ***Information Technologie***s, Inc. or GE Healthcare.
- Service or service personnel refers to service personnel trained by Innokas Medical or a service provider trained and authorized by Innokas Medical.
- In this manual, the VC150 vital signs monitor is referred to as the monitor.
- Names of physical or hardware keys on the equipment are written in **bold** typeface: **Reset** switch.
- Menu items are written in ***bold italic*** typeface: ***Monitor Setup***.
- Emphasized text is in *italic* typeface.
- Menu options or control settings selected consecutively are separated by the > symbol: ***Monitor Setup > NIBP.***
- When referring to different sections in this manual, section names are enclosed in double quotes: “Cleaning and care.”
- The word “select” means choosing and confirming.
- Messages (alarm messages, informative messages) displayed on the screen are written inside single quotes: '***Learning***.'
- Note statements provide application tips or other useful information.
- Any illustrations appearing in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your monitor.
- Any names appearing in examples and illustrations are fictitious. The use of any real person’s name is purely coincidental.

Service requirements

If your product requires warranty, extended warranty or non-warranty repair service, contact Innokas Medical Technical Support or your local Innokas Medical representative. To facilitate prompt service in cases where the product has external chassis or case damage, please advise the representative when you call.

The representative will record all necessary information and will provide a Return Authorization Number. Prior to returning any product for repair, a Return Authorization Number must be obtained.

Follow the service requirements listed below.

- Refer equipment service work only to service personnel trained and authorized by Innokas Medical.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to local Innokas Medical service or service provider authorized by Innokas Medical.
- Failure on the part of the responsible individual, hospital or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Regular maintenance, irrespective of usage, is essential to ensure that the equipment will always be functional when required.

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2 Product overview

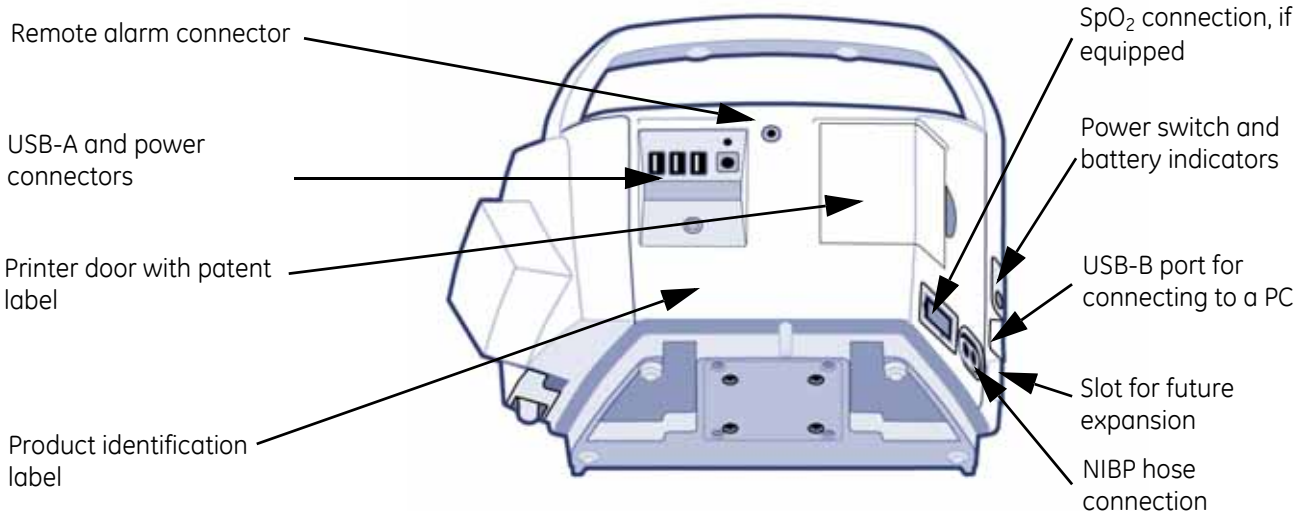
Front view

The VC150 monitor display is a touch screen where screen items are selected by pressing the touch panel with a fingertip.

CAUTION

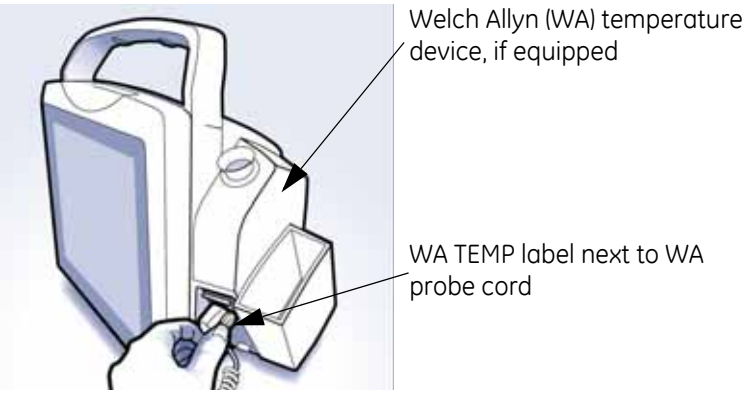
Do not scratch the screen or press the screen with a sharp object. Do not use excessive force on the screen.

Rear view and left side



Right side

A monitor with the Exergen temperature technology configuration setting cannot perform Welch Allyn temperature measurements and vice versa. If the monitor has a Welch Allyn frame installed on the right side of the monitor, then the monitor uses Welch Allyn temperature technology.



If the monitor does not have the Welch Allyn frame installed, then there are two alternatives.

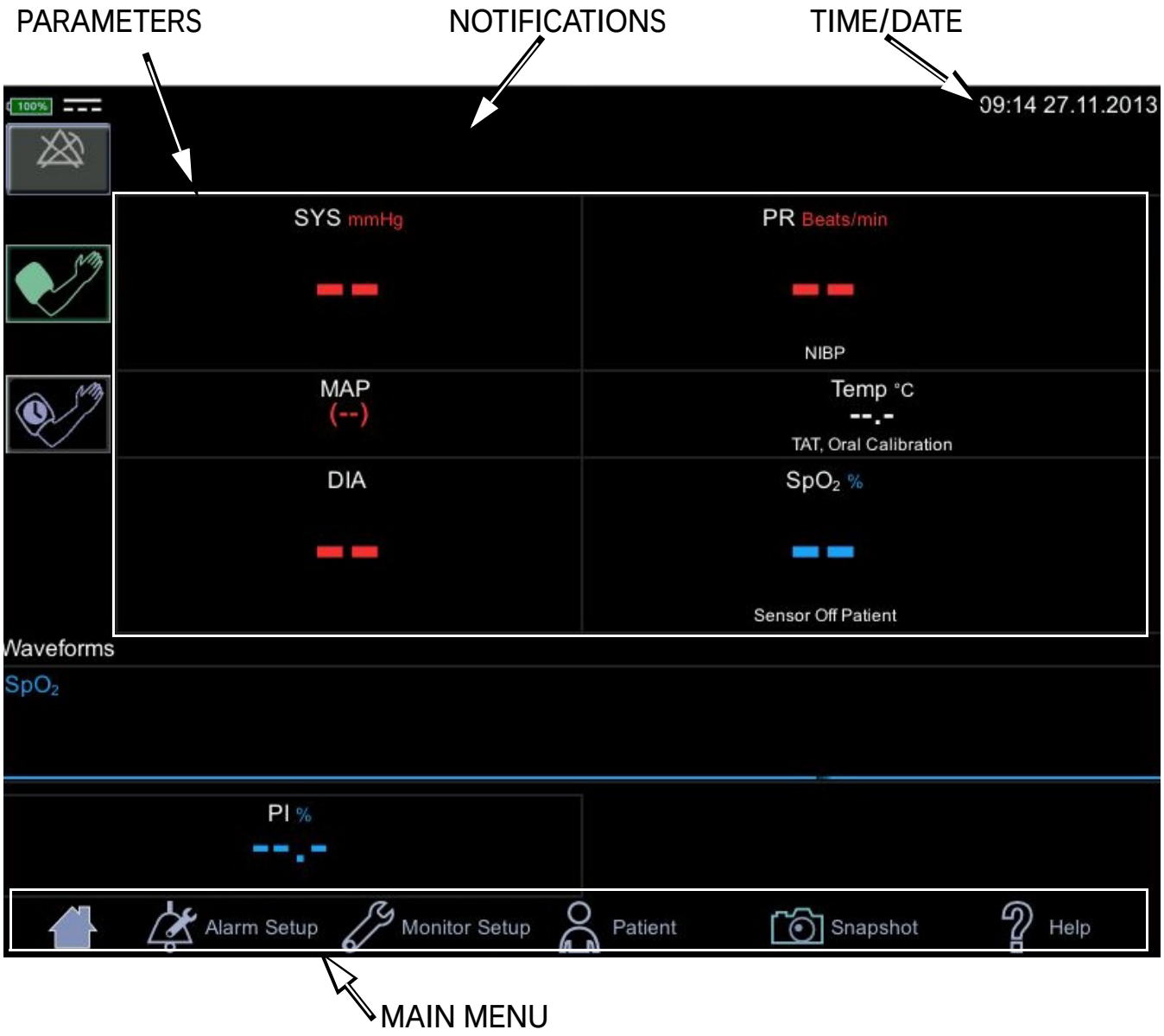
1. Exergen technology has been ordered and the monitor is configured for use of Exergen.

or

2. No temperature measurement has been ordered for the monitor.

User interface and connections

The VC150 screen design is divided into different sections that are covered more in detail in the tables below.

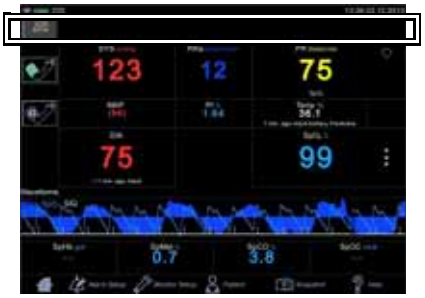


Technical information and clinical information

Icon/Text	Information displayed
	Battery low (color: red).
	DC connected.
	Battery charging (color: green).
	Battery charge level.
	Battery failure.
	WLAN is active.
	Connecting to WLAN.
	No WLAN available.
Name	Patient name Service can select following format for the patient name: • Show both last and first name, or either one if available. • Show only last name. • Show only first name. • Show only identification. • Show last name and initial for the first name.
Time and Date	Time and Date

Notification area

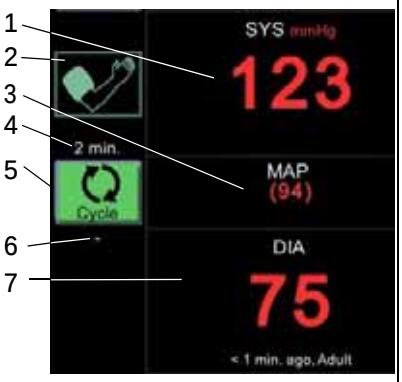
Alarm and technical messages are displayed in the notification area. The alarm and indicators are active only in monitoring mode.

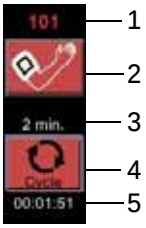
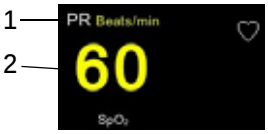
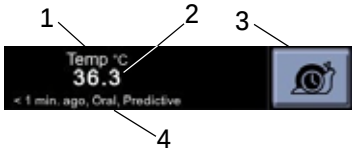


Icon/Text	Information displayed
	Audio alarms are enabled. Action icon for silencing alarms.
	Indication that alarms are silenced. A countdown timer underneath the indicator displays the remaining time for the silence.
	Indication that alarms are disabled in spot-check mode.

Parameters

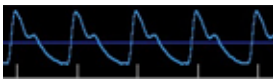
Menu selections for SpO_2 settings are different depending upon the purchased SpO_2 technology, additional licenses and selections in the ***Monitor Setup > SpO$_2$*** screen. The screen automatically adjusts to ambient light conditions by toggling between day and night brightness settings. Default expiration time for measurement data on screen is 15 minutes. This can be adjusted in the configuration mode.

Parameters	
Icon/Text	Information displayed
	1. Systolic blood pressure and unit of measurement. 2. Inflate icon to start a single measurement or additional measurement between automated measurements. 3. Mean arterial blood pressure (MAP). 4. Selected cycle/interval. 5. Cycle icon to select and start automated ***STAT***, ***Cycle*** or ***Profile*** measurements after the selection. 6. Time to next automated measurement. 7. Diastolic blood pressure, time of last measurement and patient type.

Parameters	
Icon/Text	**Information displayed**
	Screen during an NIBP measurement: 1. Cuff pressure in mmHg. 2. Icon to cancel series of automated measurements. 3. Selected cycle/interval. 4. Animation for cuff inflation. 5. Time to next automated measurement.
	1. Measured parameter and unit of measurement (SpO_2 and % as example here). 2. Measured value or dashes "--" if no value is available. 3. Measurement site (if applicable) and technical error message (if error condition active).
	Perfusion index indicated by a numeric value.
	1. Parameter: Pulse Rate (beats per minute). 2. The actual pulse rate.
	1. Body temperature (optional). 2. The actual measured value. 3. Snail icon to select monitor mode (Welch Allyn thermometry). Turns to an animated indicator when monitoring mode is active. 4. Time since last measurement and measurement site.
	1. Respiration Rate (optional). 2. The actual measured value.
	Signal quality indicated by asterisks Source: Perfusion Index (TruSignal and Nellcor) and SIQ (Masimo)

Graph area

An optional plethysmographic waveform is displayed in the graph area. If the monitor is equipped with Masimo SpO_2 technology, an RRa curve can be displayed with the waveform.

Graph area	
Icon/Text	**Information displayed**
	Plethysmographic waveform (Pleth).
	Plethysmographic waveform with Masimo RRa curve.

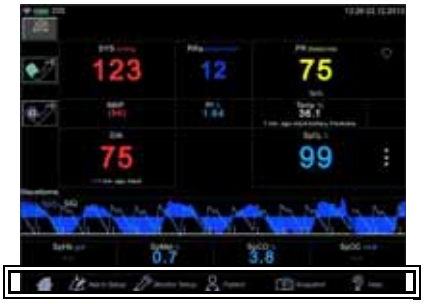
Masimo data bar (optional)

Optional data from Masimo SpO_2 technology is displayed in the Masimo bar at the bottom of the screen.

Masimo data bar (optional)	
Icon/Text	**Information displayed**
	Total hemoglobin concentration (optional).
	Fractional methemoglobin concentration (optional).
	Fractional carboxyhemoglobin concentration (optional).
	Total arterial oxygen content (optional).

Main Menu

The main menu bar contains icons to navigate within the user interface.



Main menu	
Icon/Text	Information displayed
	The home icon is used to close the active monitor setup menu screen and revert the monitor to the main screen where the patient's measurements are displayed.
	Alarm Setup is used to adjust for various alarm settings and select between spot-check and monitoring modes.
	Monitor Setup is used to access a screen where you can configure and adjust monitor operation.
	Patient is used to access stored measurements, and manage patient and caregiver identity.
	Snapshot is used to store parameter measurement data into local patient history.
	Help is used to access an index screen of topics and a context sensitive help.

Operating modes

The monitor has following modes of operation:

- Clinical mode
  - ***Spot-check mode***
  - ***Monitoring mode***
- Configuration mode with three levels of access:
  - ***Monitor Setup*** for settings by any user.
  - ***Default Setup*** (password-protected area) for settings by someone at the hospital or care unit that has the training and authority to set up default settings for the monitor.
  - ***Service Mode*** (password-protected area) for additional configuration, calibration and maintenance of the monitor.

  CAUTION
  Service Mode is intended for use by qualified and trained service personnel only.

Clinical mode

Clinical mode screen

The clinical mode starts right after the monitor is turned on. When the home screen appears and two beeps are heard, a patient's vital signs can be monitored.

The clinical mode will end when the monitor is put into standby, the monitor is shut down, or ***Service Mode*** is entered. During ***Monitor Setup*** and ***Default Setup***, monitoring processes continue in the background. The clinical mode resumes after selecting the home icon. 
In the clinical mode, all parameters are available for monitoring and user settings can be adjusted. Alarm limits are available only in monitoring mode, not in spot-check mode.

Spot-check mode and monitoring mode

Clinical spot-check mode (sometimes called manual mode) is intended for brief examinations, while clinical monitoring mode is intended for longer examinations. In spot-check mode, alarms are not active. In monitoring mode, alarms are active. The mode is selected in the ***Alarm Setup*** screen.

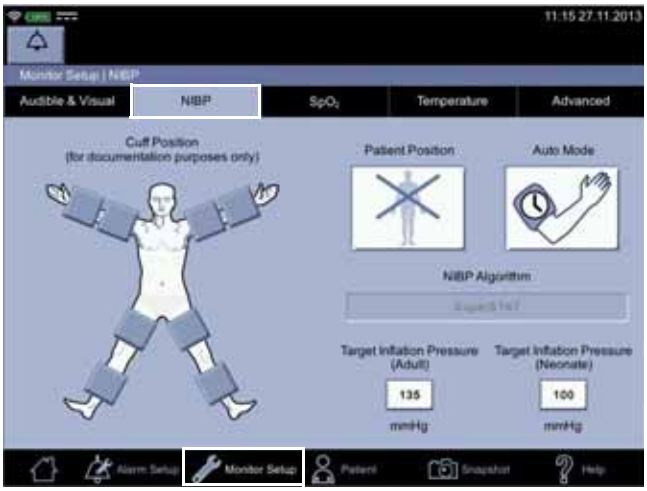
Monitor configuration

The monitor has three types of settings:

1. The current settings, which can be adjusted by the regular user. This is reset each time a patient is changed.
2. The current default settings, to which the monitor returns upon starting a new patient. These defaults can be changed only in the configuration mode.
3. Factory defaults for alarm settings on the monitor when it is first received by the customer. Service can revert alarm settings to factory defaults if necessary.

All users can access ***Alarm Setup***, ***Monitor Setup*** and ***Patient*** to configure or customize user-preferred default settings for measurements in clinical mode.

When a menu icon is selected, the related menu screen will be displayed, the menu item will be highlighted and other menu items dimmed. That indicates you are in that section.



Current settings or default settings can be adjusted while a patient is being monitored, but new examinations cannot be initiated while in the configuration mode and the parameter data will not be displayed on screen until the user returns to clinical mode. The name of the menu screen is displayed on the upper left section of the screen.

Alarm setup

The alarm limit adjustment allows you to change upper and lower alarm limit settings used on individual parameter items while monitoring a patient. If a parameter alarm limit has been set OFF in the configuration mode, color of the alarm limit on the ***Alarm Setup*** screen is displayed as gray and cannot be adjusted. Also, you can select spot-check or monitoring mode here. Refer to "Alarm limit setup" on page 3-14 for instructions. Depending on the purchased licenses for options, the screen items will vary.

NOTES

- There are no alarm limits and no clinical alarm messages for temperature measurement.
- All changes are temporary and return to the default configuration settings when the monitor is turned off or a new patient is admitted. To permanently change the alarm settings refer to "Configuration mode settings" on page 3-12.

WARNINGS

Monitors located in the same clinical area may contain different alarm default settings, which can result in a potential hazard.

Always check your alarm settings before using the monitor.

Caution should be taken to not set alarm limits to extreme values, as this can render the alarm system useless.

Monitor Setup

Monitor Setup consists of four tabs that all users are allowed to configure. These configurations are only for the current patient. To make these changes permanent, these must be changed in the configuration mode.

Audible & Visual is used to configure alarm and display brightness and sound settings. Refer to "Audible & Visual" on page 3-19 for more information.

NIBP is used to select cuff position, target inflation pressures and patient position. Refer to "NIBP" on page 6-1 for more information.

SpO_2 is used to select measurement site and visual elements of the SpO_2 parameter in clinical mode. Refer to "GE TruSignal SpO2" on page 7-1, "Masimo SpO2" on page 8-1 and "Nellcor SpO2" on page 9-1for more information.

Temperature is used to configure temperature measurement. Refer to "Temperature setup" on page 3-25 for more information.

Default Setup

Password-protected ***Default Setup*** is used for a more advanced configuration for ***General***, ***Alarm Defaults***, ***Visual Settings*** and ***Measurement settings***. It is intended for someone at the hospital or care unit that has the training and authority to configure default settings for the monitor. Refer to "Default setup" on page 14-1 for configuration instructions. Availability of configurable features depends on what parameter-related options have been ordered. Changes applied in ***Default Setup*** remain set even if the monitor is switched off.

Patient

Patient- and caregiver-related data in ***Patient*** can be accessed for the following:

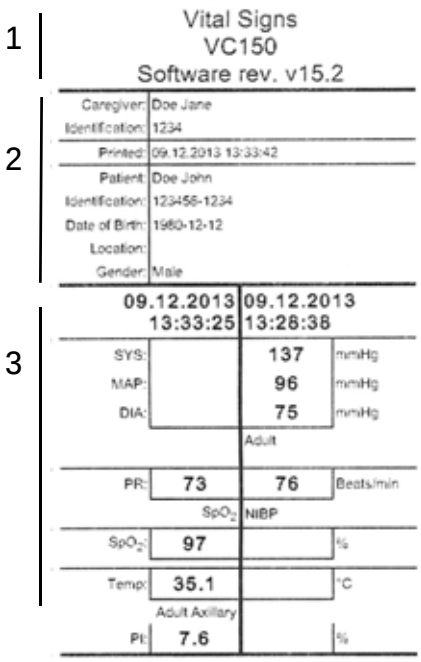
- Entering patient information and searching for patients
- Logging the caregiver on and off
- Viewing, editing and sending snapshots

NOTE

Refer to "Patient and caregiver data" on page 5-1 for more information.

Printout

The printer is an optional feature of the monitor. If your monitor contains a printer, each time a printout is started the following information is printed. Contents of the printout can be selected in the ***Patient*** screen.



Item	Name
1	Monitor name and model number. Current software revision. The software revision letters map to a numeric software revision.
2	Patient name. Time of printing. Information about the patient and care facility.
3	Snapshot • Left side: printer line headings. • Middle: Vital signs information is displayed as a snapshot (or collection) of all available data at the time. Two different shapshots can be printed side by side with the monitor strip printer. Non-continuous values such as NIBP, predictive temperature and Exergen temperature are automatically captured when the measurement is completed. Continuous values (SpO_2 and temperature in the monitor mode) are stored with the ***Snapshot*** icon. Printed contents vary depending on which SpO_2 or temperature technology is used to provide the data. • Right side: Units of measurement.

Remote Management

Some service work can be done through remote service interface.

WARNING
Do not use the monitor for clinical measurements during remote service session.

The following applies to the remote service:

- ***Start Remote Service*** icon is selected in ***Monitor Setup > Advanced.***
- A remote service active screen displays the IP address of the monitor, ***Waiting for Service User actions*** and ***Cancel***. If service is logged on, the monitor displays ***Remote User active, please do not turn the monitor off!*** and no ***Cancel*** on the screen.
- Remote service is stopped after 5 minutes of inactivity.
- If completion of service work requires restarting the monitor, the remote service is not restarted automatically.

Battery low shutdown or system failure

If battery power is nearly depleted or the system detects a serious failure, the monitor will not allow new examinations and will shut down. Refer to "Alarms" on page 4-1 for details and alarm messages.

Sounds

The monitor generates sounds to indicate parameter events, and physiological or technical alarms.

Battery charger sounds

Whenever the external DC charger is connected and disconnected, the monitor sounds a short tone.

Essential performance

The VC150 vital signs monitor measures physiological parameters within specified accuracy limits, raises alarms based on user-defined conditions, or generates either a technical alarm or an indication of abnormal operation.

The measurement ranges and accuracies depend on the measurement technology and are summarized in the table below.

GE TruSignal SpO_2 accuracy and ranges	
Measurement range	
SpO_2 saturation range	0 to 100%
Pulse rate range	30 to 300 bpm
Measurement accuracy	
SpO_2 saturation accuracy	70% to 100% ±2 to ±3 digits
Pulse rate accuracy	30 to 250 bpm ±2 bpm to ±5 bpm (rms)

Nellcor™ Sensor accuracy and ranges	
Measurement range	
SpO_2 saturation range	1% to 100%
Pulse rate range	20 to 250 bpm
Respiration rate range	4 to 40 breaths/minute
Measurement accuracy	
SpO_2 saturation accuracy	70% to 100% ±2 to ±3.5 digits
Pulse rate accuracy	20 to 250 bpm ±3 bpm (rms)

Masimo rainbow SET® sensor accuracy and ranges	
Measurement range	
SpO_2 saturation range	0 to 100%
Pulse rate range	25 to 240 bpm
SpCO range	0 to 99%
SpMet range	0 to 99.9%
SpHb range	0 to 25 g/dl
Respiratory Rate range	0 to 70 breaths per minute
Measurement accuracy	
SpO_2 saturation accuracy	70% to 100% ±2% to ±3%
Pulse rate accuracy	25 to 240 bpm ±3 to ±5 bpm (rms)
Respiration rate accuracy	4 - 70 ± 1 breath per minute
SpCO accuracy	1 - 40 ± 3%
SpMet accuracy	1 - 15 ± 1%
SpHb accuracy	8 - 17 ± 1 g/dl (arterial or venous)

NIBP accuracy and ranges	
Measurement range (Auscultatory algorithm)	
Systolic BP range	30 to 245 mmHg (adult/ped)
MAP range	15 to 215 mmHg (adult/ped)
Diastolic BP range	10 to 195 mmHg (adult/ped)
Pulse rate range	30 to 200 beats/min (adult/ped)
Measurement accuracy (Auscultatory algorithm)	
Blood pressure accuracy	mean error ≤ 5 mmHg, standard deviation ≤ 8 mmHg
Pulse rate accuracy	± 3.5% or 3 bpm, whichever is higher
Measurement range (SuperSTAT algorithm)	
Systolic BP range	30 to 290 mmHg (adult/ped) 30 to 140 mmHg (neonate)
MAP range	20 to 260 mmHg (adult/ped) 20 to 125 mmHg (neonate)
Diastolic BP range	10 to 220 mmHg (adult/ped) 10 to 110 mmHg (neonate)
Pulse rate range	30 to 240 beats/min (adult/ped) 30 to 240 beats/min (neonate)
Measurement accuracy (SuperSTAT algorithm)	
Blood pressure accuracy	mean error ≤ 5 mmHg, standard deviation ≤ 8 mmHg
Pulse rate accuracy	± 3.5% or 3 bpm, whichever is higher

Welch Allyn temperature accuracy and ranges	
Measurement range	
Patient temperature range	26.7° C to 43.3° C (80.0° F to 110.0° F)
Measurement accuracy	
Monitor mode temperature accuracy	±0.1° C; ±0.2° F

Exergen temperature accuracy and ranges	
Measurement range	
Temperature range	16° C to 43° C (61° F to 110° F)
Measurement accuracy	
Temperature accuracy	±0.1° C (±0.2° F)

Product specifications

Mechanical	
Dimensions	
Height	24.7 cm (9.75 in)
Width	24.2 cm (9.5 in) without Welch Allyn temperature 29.2 cm (11.5 in) with Welch Allyn temperature
Depth	13.6 cm (5.3 in)
Weight (including battery)	2.8 kg (6.2 lb)
Mountings	Tabletop (self-supporting on rubber feet), mounted on a roll stand or a wall mount bracket
Portability	Carried by handle
Power requirements	
Universal power converter	PN: MO000145

Protection against electrical shock	Class I
AC input	100 - 240~1.1A
DC output voltage	24 VDC at 2A The AC mains power adapter contains a non-resettable and non-replaceable fuse.
Rated supply frequency	50 - 60 hZ
Monitor	
Screen	Resistive touch screen
Protection against electrical shock	Internally powered or Class I when powered from specified external medical power supply.
DC input voltage	24 VDC, supplied from a source conforming to IEC 60601-1.
Fuses	The monitor contains two T3.5A replaceable fuses on the mother board (F3) and USB board (F1). The battery packet contains overcurrent and temperature protection. The fuses protect the low voltage DC input and the main battery.
Main battery	Refer to "Monitor battery specifications" on page 13-6.
Environmental	
Operating temperature	Without temperature sensors: 5 to 40° C (41 to 104° F) With Welch Allyn temperature sensor: 10 to 40° C (50 to 104° F) With Exergen temperature sensor: 16 to 40° C (61 to 104° F)
Humidity range	5% to 95% non-condensing
Operating atmospheric pressure	700 hPa to 1060 hPa
Storage/transport	
Storage temperature	– 20° C to + 50° C (– 4° F to + 122° F)
Atmospheric pressure	500 hPa to 1060 hPa
Humidity range	5% to 95% non-condensing

Printer specifications

Printer type	Thermal dot array
Resolution	384 dpi horizontal
Paper type	The paper roll used by the printer must be compatible with 32018145.
Languages printed	All user interface languages.

Connectivity specifications

Wireless specifications	
WLAN connection standard	802.11 standard (a/b/g/n)
WLAN speed	Maximum: a 54 Mb/s b 11 Mb/s g 54 Mb/s n 150 Mb/s
WLAN output level (Effective Radiated Power, ERP)	2.4 GHz 10 dBm 5 GHz 13 dBm
WLAN bands	Capable of communicating on 2.4 GHz and 5.1 GHz bands.
The allowable range of DSCP values per Access Category for interoperability between WMM-compliant clients	Non-realtime clinical data: 0 7 Non-realtime, non-clinical data: 8 23
Use of general-purpose WLAN network	No dedicated wireless network required.
WLAN encryption methods	None WEP WPA-PSK WPA-EAP WPA Custom
Authentication	WEP: Open System, Shared Key WPA-PSK: WPA-TKIP, WPA2-AES WPA-EAP: TLS, TTLS, PEAP, FAST WPA Custom: free configuration within limits of linux/wpasupplicat support
Number of SSID profiles	Up to 4 SSID profiles that service can define and configure.

Wireless specifications	
WLAN frequency band settings	■ 2.4 GHz band ■ 5.1 GHz band ■ 2.4 & 5.1 GHz bands
Modulation	OFDM (802.11a/g/n), DSSS/CCK (802.11b)
WLAN information displayed	Transmit power (dBm) SSID RTS Threshold Fragmentation Threshold IP Address Bit Rate Link Quality Noise Level Signal to Noise Ratio Signal level (RSSI) in terms of dBm Network adapter MAC address Other WLAN info
EMC Compliance	Complies with IEC Publication 60601-1-2 Medical Electrical Equipment, Electromagnetic Compatibility Requirements and Tests and CISPR 11 (Group 1, Class B) for radiated and conducted emissions.
Access point information displayed	Access point radio frequency Access point radio MAC address (BSSID)
RF information displayed	Radio frequency (i.e., the frequency associated with the channel number) Transmit power in terms of dBm Signal level (RSSI) in terms of dBm
Radio diagnostic information displayed (counters can be reset)	Packets received Packets transmitted Bytes received Bytes transmitted Receiving errors Transmission errors

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3 Getting started

Introduction

This chapter provides an overview of monitor operation and accessories. Before attempting to use the monitor, take a few minutes to become acquainted with the monitor and its accessories. Unpack the accessory items carefully. This is also a good time to check for any damage or accessory shortage. If there is a problem or shortage, contact Innokas Medical.

It is recommended that all the packaging be retained in case the monitor must be returned for service in the future.

NOTE

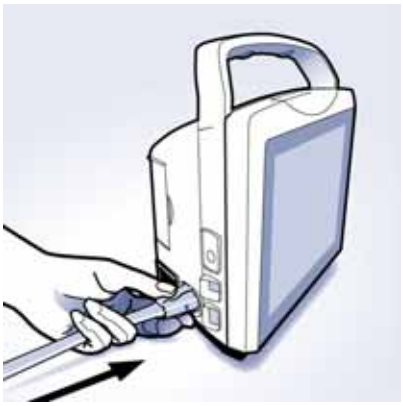
The monitor cannot be used before the battery is installed. Only service personnel may remove and install the battery.

Setting up NIBP connections

1. Connect the end of the air hose that has quick-release clips to the NIBP connector on the left side of the monitor (the touch screen being the front part). Make sure that the hose is not kinked or compressed.

   NOTE

   To disconnect the hose from the monitor, squeeze the quick-release clips together and pull the plug from the NIBP connector.



2. Select the appropriate cuff size.
   Measure patient's limb and select an appropriately sized cuff according to size marked on the cuff or cuff packaging. When cuff sizes overlap for a specified circumference, choose the larger size cuff.

   WARNING

   Selecting a correct hose and cuff is ***very*** important. ***Do not mix neonatal and adult hoses! An adult hose pressure is extremely dangerous for neonates.*** The air hoses are color-coded according to patient population. The gray 12- or 24-foot hose (3.66 m or 7.3 m) is required on patients who require cuff sizes from infant through thigh cuffs. The light blue 12-foot hose (3.66 m) is required for the neonatal cuff sizes #1 through #5.

   Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and to select the proper size cuff. If it becomes necessary to move the cuff to another limb, make sure the appropriate size cuff is used.

CAUTION
The RADIAL-CUF has been validated for use only with GE SuperSTAT algorithm for adult obese patients. The RADIAL-CUF has not been validated for use against the GE Auscultatory algorithm. Refer to the RADIAL-CUF instructions for use for sensor requirements.

3. Inspect cuff/adapter/air hose for damage. Replace cuff when aging, tearing, leaks or weak closure is apparent. Do not inflate cuff when unwrapped.

   CAUTIONS
   Incorrect cleaning procedures will contaminate the accessory or shorten lifetime of the cuffs or hoses. Clean according to the specific cleaning and disinfection instructions provided with the accessory.

   Do not use cuff if structural integrity is suspect.

4. Connect the cuff to the air hose. Refer to "NIBP" on page 6-1 of this manual for complete cuff connection instructions.

   CAUTION
   Always use the appropriate hose and cuff combination for the patient. Any attempt to modify the hose may prevent the monitor from switching between the neonate and adult/pediatric measurement modes.

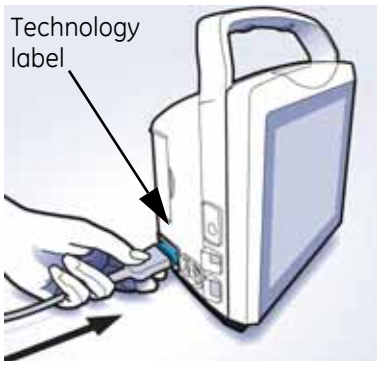
   NOTE
   Ensure the cuff and the hose are securely connected. Make sure no leak occurs.

5. Refer to "NIBP" on page 6-1 of this manual for complete instructions on taking an accurate NIBP determination.

   NOTES
   - Use only GE BP cuffs. The size, shape, and bladder characteristics can affect the performance of the instrument. The accuracy of the DINAMAP blood pressure algorithm has only been confirmed when used with GE cuffs. Refer to the VC150 supplies and accessories document for order part numbers.
   - When the monitor displays ***Adult*** in ***Monitor Setup > NIBP***, it encompasses both adult and pediatric patients.

Setting up SpO_2 connections

1. Check the SpO_2 technology used (Masimo, GE TruSignal or Nellcor) on the label above the connector. If you cannot read the label, ask the nurse manager or service what SpO_2 technology is used.
2. Depending on the sensor type, plug a SpO_2 sensor into the SpO_2 sensor extension cable or directly to the monitor.
3. If needed, plug the SpO_2 sensor extension cable into the SpO_2 sensor connector on the monitor.



Refer to the "SpO_2" section of this manual for complete instructions on monitoring SpO_2.

CAUTION

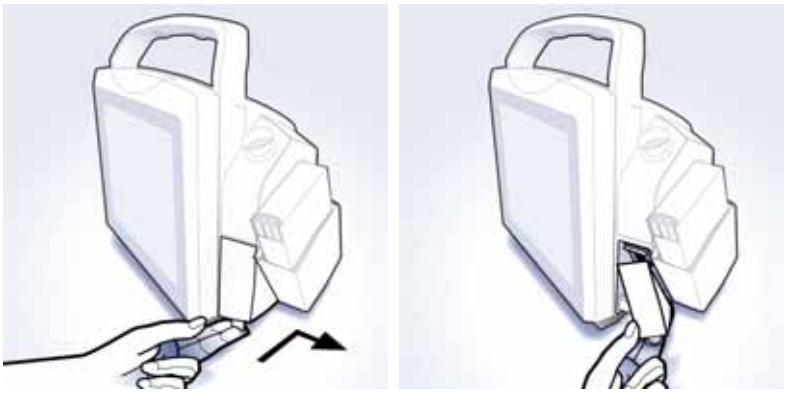
Never use any other technology than what is stated on the label. Connectors of cables used with other SpO_2 technologies may fit the monitor SpO_2 connector, but these must ***not be*** used.

Setting up temperature connection

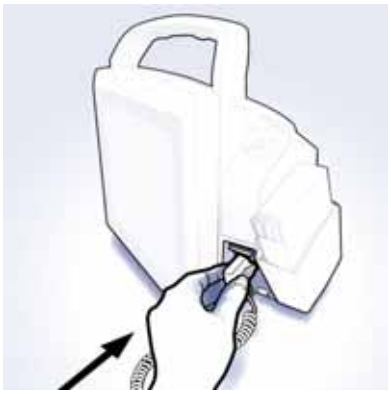
Welch Allyn (optional)

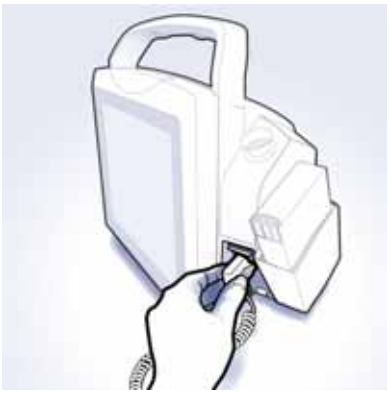
If the monitor is equipped with Welch Allyn temperature, follow instructions below. The probe connector is located under the cover.

1. Remove the cover.



2. Plug in the temperature probe.





3. Replace the cover.

4. Insert the temperature probe into the probe well at the side of the monitor.

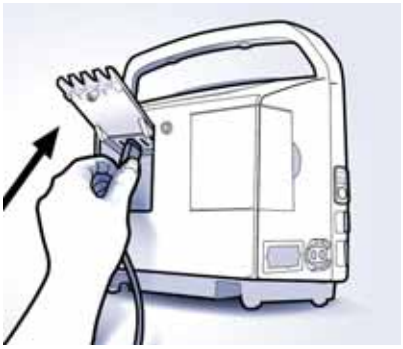
NOTE

A probe for oral and axillary measurement has a blue ejection button that pairs with a blue probe well. A probe for rectal measurement has a red ejection button that pairs with a red probe well. Although the detection mechanism at the probe well allows the Welch Allyn device to recognize the used probe, always ensure that the probe and the probe well colors match.

5. Refer to "Welch Allyn temperature" on page 11-1 of this manual for complete instructions on taking a temperature reading.

Connecting USB accessories

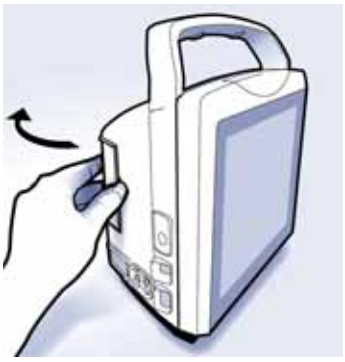
1. Open the USB hatch at the back of the monitor.
2. Connect the accessories.
3. Close the hatch and secure the cables by tightening the knob.

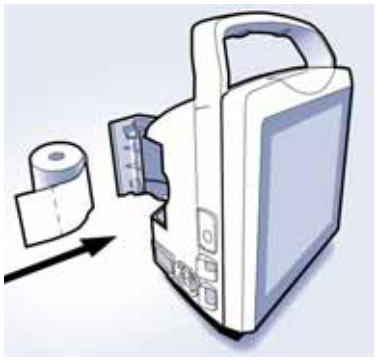


Installation/replacement of printer paper

If the optional printer is available, follow these steps to install or replace the paper.

1. With the monitor powered off, turn it so that the side with the printer is facing you.
2. Place your thumb on the indented area of the printer door, then pull it out. The printer door will pop open.





3. Place the roll of paper into the compartment so that the end of the paper comes off on the right side of the roll (rotates clockwise). Place the roll of paper in the holding bracket that is integrated in the door of the printer, making sure the paper extends out of the printer cavity at least 5 cm (two inches).
4. Firmly press the door to close it.

Paper storage

Store thermal paper in a cool, dry place. The printed strip (thermal paper recording) should not be:

- Exposed to direct sunlight
- Exposed to temperatures over 38° C/100° F or relative humidity over 80%
- Placed in contact with adhesives, adhesive tapes, or plasticizers such as those found in all PVC page protectors

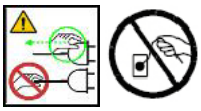
NOTES

When in doubt about long-term storage conditions, store a photocopy of the thermal paper recording.

The paper is thermally activated; therefore, do not store it in a hot place as discoloration may result.

Use only replacement paper rolls (pn 32018145 for box of 10) ordered from your Innokas Medical representative.

Electrical connection



Connect the supplied power cord to the mains power. Use only the original cord or a cord listed in the VC150 supplies and accessories document for the country of use.

Power sources

Refer to "Monitor battery specifications" on page 13-6 for details. With external DC power connected, the green charging indicator will light to indicate that the battery is charging.

DANGER

ELECTRIC SHOCK — Do not touch the patient and the DC power input connector pins simultaneously.

WARNING

Examine the power cord periodically. Discontinue use and replace if damaged. Replace the power cord, as necessary, with a cord listed in the VC150 supplies and accessories document for the country of use.

NOTE

Be sure to unplug the power supply from the AC outlet before transport.

Monitor on/off

NOTE

For safety reasons, the monitor is designed so that it can be powered without a battery while its power supply is connected to mains. However, clinical mode is not possible without a functional internal Lithium battery specified for VC150.

WARNING

Inspect the device for damage before use.

1. Push the power **On/Off** button on the left side of the monitor to turn it on. During power-up, the monitor displays the software version on a white power-up screen with grayish blue borders. The monitor will also flash the alarm light at the top. After the monitor has completed the start-up sequence, there will be two short tones and the opening screen changes to the home screen.

NOTES

If the monitor fails to sound the start-up tones, or the alarm lights do not blink in three colors during start-up, do not use the monitor. This indicates problems with the audible alarm circuit or alarm lights. Potential alarms cannot be heard or seen. Contact service.

If the power-up screen does not change to the home screen within 2 minutes, contact service.

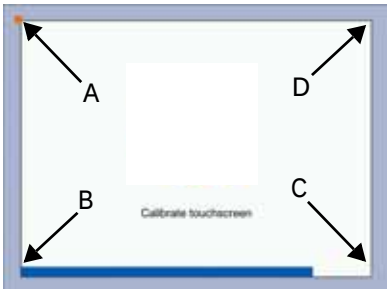
2. If you notice that selections do not accurately track the position of your finger, it is possible to recalibrate the touch screen on this device during power-up. Refer to "Touch screen recalibration" on page 3-9.

Touch screen recalibration

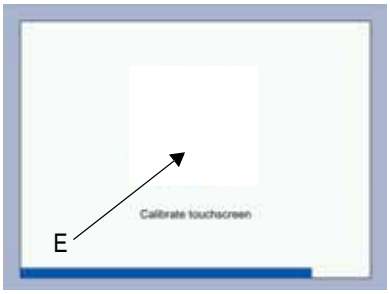
1. To recalibrate the screen, turn off the monitor and turn it on again.
2. Wait until a blue progress bar has extended over a half of its total length. The monitor will display the current software version and the text ***Touch to recalibrate***. Now press anywhere on the white screen area for three seconds to begin the recalibration process. You can also press power button shortly to begin recalibration.

NOTE

If the blue progress bar reaches the end and the black home screen appears, you have to start the monitor again to recalibrate it.



3. You can start the recalibration when a blinking rectangle appears in the top left corner (A).
4. Press the rectangle to select it. Hold your finger down for a moment, if necessary. If the software registered the selection, the rectangle moves to the next location.
5. Select the rectangle at each location (B, C, D and E).



NOTE

Do not slide your finger on the screen. Selections are made by pressing the screen with your fingertip and then lifting the finger away from the screen.

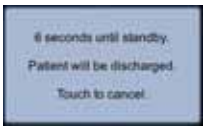
6. When the recalibration is complete, the home screen will appear and you can continue using the monitor.

Verification of the touch screen recalibration

1. Select ***Help***.
2. Close the help screen with ***Close***.
3. Select the systolic NIBP area to jump to the NIBP screen.
4. Select the home icon to exit the NIBP screen.

If you are not able to perform the commands because the calibration is still off, try again to recalibrate. If even the new calibration does not solve the issue, contact service.

Standby



The monitor has an automatic standby feature in order to conserve battery life. If the monitor is in clinical mode and has been inactive for a period of time, the screen turns black and the monitor switches to standby mode. Within first two minutes of standby, you can activate the monitor again by touching the screen. After two minutes of standby, press the **On/Off** button to activate the screen again. The inactivity timer can be adjusted in configuration mode. When running on battery, the monitor is automatically shut down after 15 minutes of standby,

NOTES

Refer to "Clinical mode" on page 2-10 for a description of clinical mode.

The monitor will not automatically switch to standby mode if 1) this is disabled in configuration mode, or 2) a visible alarm (low, medium, high) is displayed on screen during monitoring mode.

The monitor switches to standby when:

- The touch panel has not been operated for a configured period of time, and
- There are no ongoing measurements.

Monitor standby

User-initiated standby

Push **On/Off** button briefly to put the monitor into a standby state. This is possible if the monitor is in spot-check mode or there are no ongoing measurements in monitoring mode.

Unless disabled by service, the monitor will automatically switch to standby mode if monitor has been idle for a configured period of time and not currently used for patient monitoring. If the monitor is disconnected and remains in standby mode for over 15 minutes, the monitor will shut down.

Resuming operation

Push the **On/Off** button again or touch the screen to resume the active clinical mode.

Turning the monitor off

If determinations are complete and the monitor will not be used for a longer period of time, push the **On/Off** button until the monitor starts to shut down (approximately 3 seconds). The same can be done also if some technical issue is impeding use of the monitor. This will invoke a shutdown note on screen, terminate any measurements that may be in progress, automatically deflate the cuff and discharge the patient.

Summary

The table below summarizes the various ways to use the **On/Off** button.

Current monitor status	Push On/Off	New monitor status
OFF	A brief push	ON
Standby		
ON		Standby, patient discharged
ON	Push and hold until the monitor starts to shut down (approximately 3 seconds).	OFF, patient discharged
Standby		

Procedure for testing alarms

1. With the monitor on, monitoring mode selected and the NIBP hose ***not*** connected to the left side of the monitor, select the inflate icon.
2. Verify that after approximately 20 seconds the alarm sounds and the monitor generates a message in the alarm area. Audible alarms are signaled also in spot-check mode if low priority alarm tone is enabled in the ***Monitor Setup > Advanced > Default Setup***. The visual indicator also appears in spot-check mode.
3. To clear the alarm, select the alarm message in the notification area.
4. Switch the monitor off and on to verify tones during power-up. Check that alarm light sequence on top of the monitor during power-up equals BLUE-YELLOW-RED, then clinical mode screen should appear. If it does not, contact service.

Configuration mode settings

Clinical defaults such as ***Upper/Lower*** alarm limits are set up in configuration mode and can be changed as needed for a given patient in the ***Alarm Setup*** screen. The limit settings always revert to the configured defaults when the power is cycled or a new patient is identified. To retain alarm and parameter settings, the changes must be done in configuration mode.

Using the numeric keypad

The numeric keypad can be used to enter numeric values, for example, in an alarm limit box.

	A numeric entry is accepted with ***Confirm***.
	An numeric entry is canceled with ***Cancel***.
	Backspace icon.
	Dash icon.
	Decimal comma icon.

Icons on the monitor

Using the home icon

Whenever the home icon is selected, the system will save changes and return to clinical mode.

List of VC150 icons	
	Alarm silenced
	Auto mode options
	Auto mode options not available
	NIBP not available
	Inflate
	Inflate waiting
	Stop inflation
	Alarm priority High/Medium/ Low/OFF
	Rectal
	Axillary
	Earlobe
	Finger

	Forehead
	Nose
	Oral
	Toe
	Prone position
	Sitting position
	Standing position
	Supine position
	Other site
	None
	Neonatal

Alarm limit setup

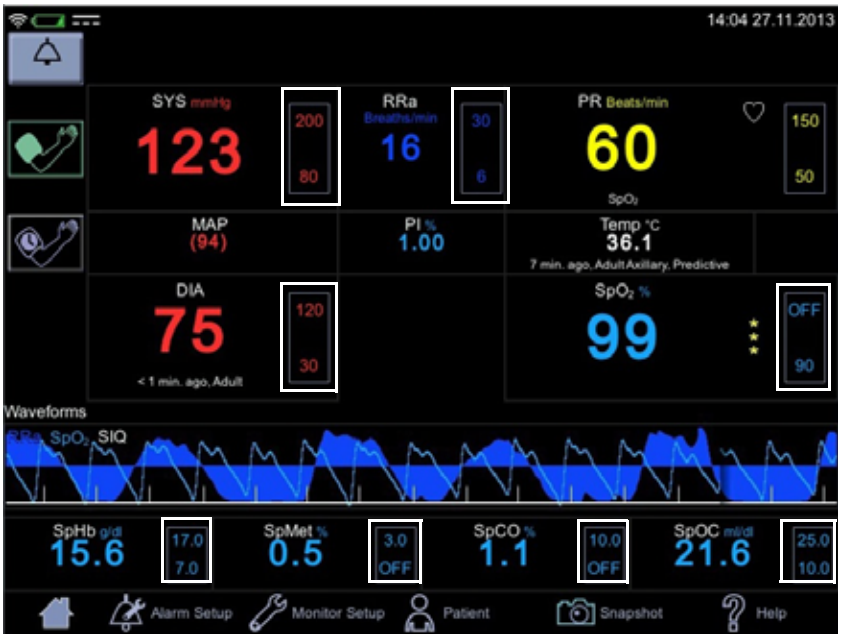
There are two methods to set up alarm limits on individual parameter items. These include selecting ***Alarm Setup*** or touching in the limit boxes within the parameter.

NOTE

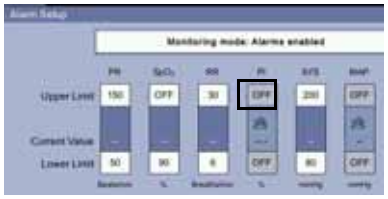
If priority for individual parameter items has been set as OFF in configuration mode, the limit box will be dimmed in ***Alarm Setup*** and cannot be changed.

Changing limits for a single parameter box

1. Touch on the top or bottom part of the limit box to change high/low limits in a single box.



2. Enter a value to set up or adjust a limit, especially for neonates and children. A value between upper and lower limits is the ***Current Value*** of the parameter (the sensors must be attached to the monitor). It is provided to assist in setting up or adjusting a limit.



NOTE

Adjust alarm limits cautiously.

3. Select ***Confirm*** key to confirm the change or select ***Cancel*** to cancel the change.
4. Adjust other limits if necessary.
5. When you are finished with the alarm setup, select the home icon to save the settings and return to clinical mode.

Changing multiple alarm limits

1. Select ***Alarm Setup***.

2. This screen will appear. Available limits vary depending on purchased licenses or SpO_2 technology used and what has been selected in ***Monitor Setup > SpO$_2$*** or ***Monitor Setup > Default Setup > Visual Settings***.

3. Touch on the top or bottom part of the limit box.
4. Enter a value to set up or adjust a limit, especially for neonates and children. A value between upper and lower limits is the ***Current Value*** of the parameter (the sensors must be attached to the monitor). It is provided to assist in setting up or adjusting a limit.

NOTE

Adjust alarm limits cautiously.

5. Select ***Confirm*** to confirm the change or select ***Cancel*** to cancel the change.
6. Adjust other limits if necessary.

7. When you are finished with the alarm setup, select the home icon to save the settings and return to clinical mode.

Nellcor feature setup

Refer to "Nellcor SpO2 configuration" on page 9-27 for more information on Nellcor features.

1. Enter ***Alarm Setup***.

2. Make the necessary selections.
3. Select the home icon to save the settings and exit the ***Alarm Setup***.

Masimo feature setup

Refer to "Masimo rainbow® SET® SpO2 configuration" on page 8-25 for more information on Masimo features.

1. Enter ***Alarm Setup***.

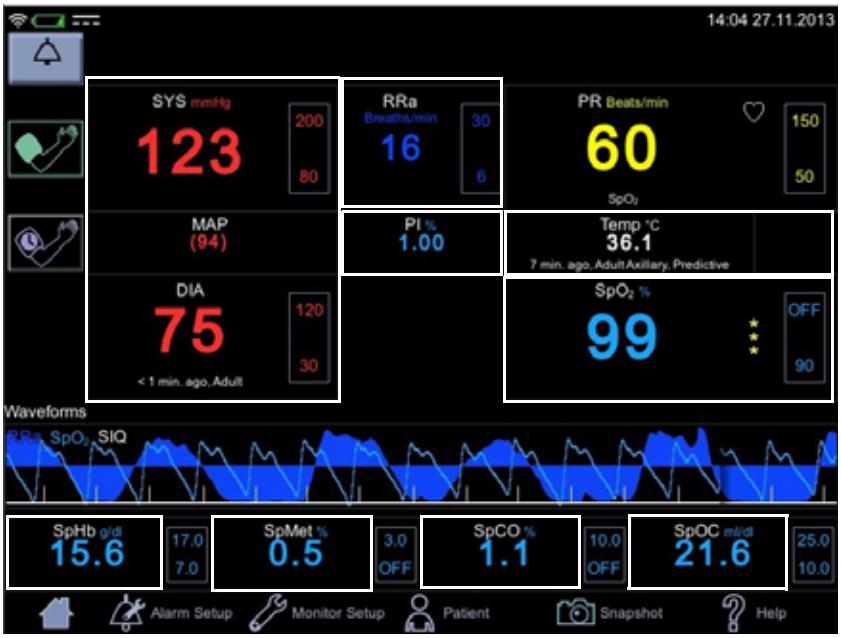
2. Make necessary selections.
3. Select the home icon to save the settings and exit the ***Alarm Setup***.

Monitor setup

Monitor setup allows you to select options or modify settings. When selected, the ***Monitor Setup*** icon is highlighted. There are 4 tabs for a normal user to choose from: ***Audible & Visual***, ***NIBP***, ***SpO_2*** or ***Temperature***.

Shortcut to setup screens

1. If you select a touch screen item (except for PR), a shortcut will take you to menu screens where you can select options or modify settings.

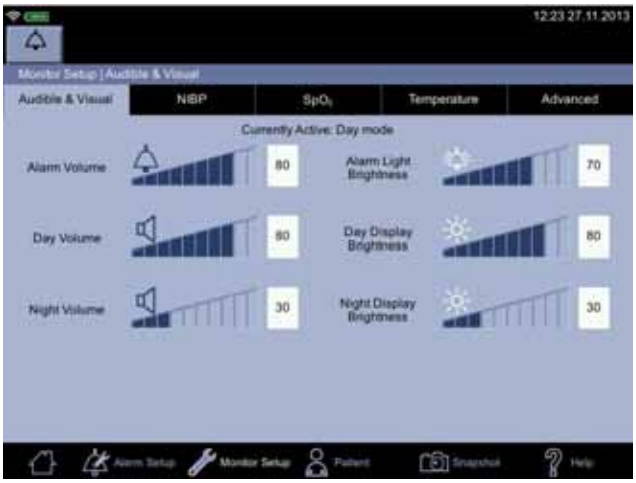


2. When you are finished with the configuration, select the home icon to return to clinical mode.

Menu selection for setup screens

1. Select ***Monitor Setup*** and subsequent tab sheets.

2. Select ***Audible & Visual***, ***NIBP***, ***SpO_2*** or ***Temperature*** to make selections or to modify the settings.

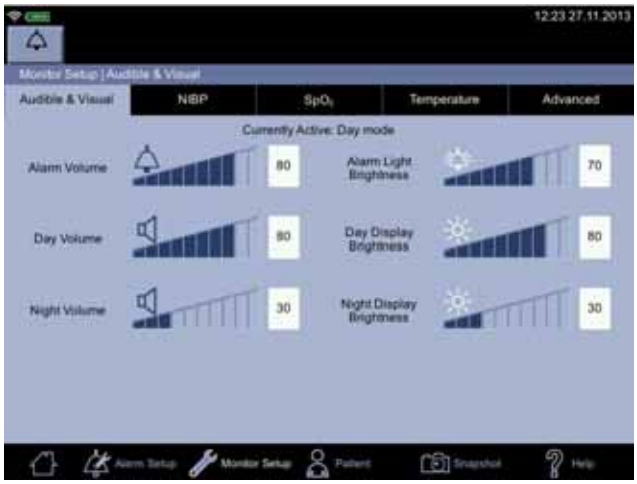


3. When you are finished with the configuration, select the home icon to return to clinical mode.

Audible & Visual

An audible signal is used to indicate the presence of an alarm limit violation. If audible signals need adjustment, these can be adjusted in the ***Monitor Setup > Audible & Visual*** screen.

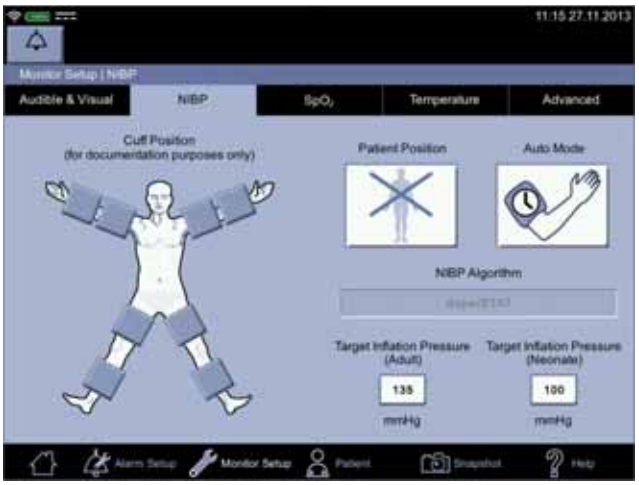
The first tab in ***Monitor Setup*** is ***Audible & Visual***. This allows you to adjust ***Alarm Volume***, ***Day Volume***, ***Night Volume***, ***Alarm Light Brightness***, ***Day Display Brightness*** and ***Night Display Brightness***. The currently active day/night mode is automatically determined by a light sensor on lower right part of the monitor touch screen. The tab sheet displays the mode for both volume and brightness above sound level bars. Sound levels can be lowered by selecting left part of the sound level bar or raised by selecting the right part of the sound level bar. These settings affect all applicable monitor screens. If the alarm sound level cannot be set as low as required, it means that the minimum alarm sound level has been set in the ***Monitor Setup > Advanced > Default Setup > General*** to be something other than 0.



Signal	Description
Alarm Volume	Controls the level of audible alarm signal at the monitor. ***Minimum Alarm Volume*** in configuration mode sets the relative lower limit, but you can adjust the sound here from 0 to 100.
Day Volume	Controls the sound level during day time use.
Night Volume	Controls the sound level during night time use.
Alarm Light Brightness	Controls the illumination level of the LEDs when an alarm message is triggered on the screen.
Day Display Brightness	Controls the level of backlight on the monitor during the daytime.
Night Display Brightness	Controls the level of back light on the monitor during the nighttime.

NIBP setup

The second tab in ***Monitor Setup*** is ***NIBP***.



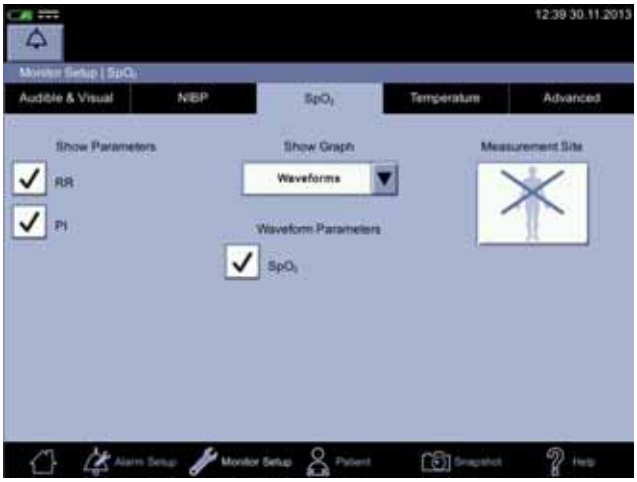
NIBP settings	Description
Cuff position and side	Rectangular sections indicate areas on the body where the cuff can be placed for NIBP measurement. Only one cuff position can be selected at the time. When a rectangle is selected, it will turn dark. If the measurement site needs to be changed, select another rectangle. If you want to cancel selection of a measurement site, select a dark rectangle to deselect it. The selected cuff position will be displayed below the diastolic value. NOTE Choosing the position of the cuff is for documentation purposes only. Whatever is selected here does not have any effect on the operation of the NIBP measurement system. Please refer to the instructions for use of the cuff for further information.
Patient position	An optional selection of patient position during measurement. 

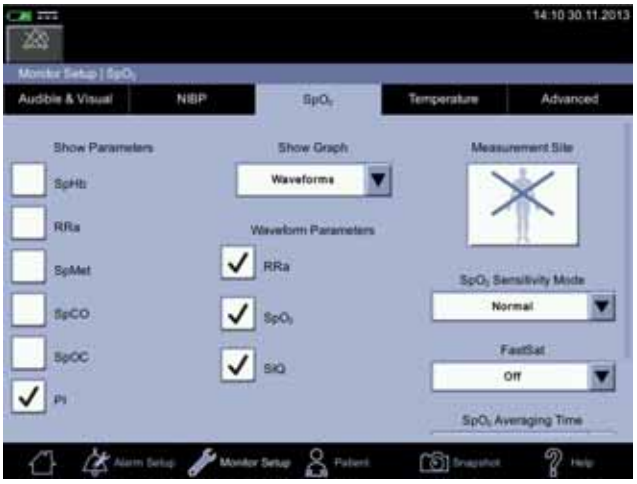
NIBP settings	Description
NIBP algorithm	Indicates the NIBP algorithm in use. Service can change it upon request.
Target Inflation Pressure Adult *Target Inflation Pressure Neonate*	Target inflation pressure is a level of pressurization that the monitor aims for when a new determination is initiated. If the patient's usual systolic value is known, a normal end user can change the target pressure to provide extra comfort. Changing this setting for either patient type is possible when no NIBP determination is active. When the patient is discharged, the monitor will revert to the default target pressure. If the monitor detects a different hose, it will revert to the most recent default target inflation setting for that hose type. The default target inflation pressure can be adjusted in configuration mode if necessary. Initial default target pressures: • Adults/children when auscultatory algorithm is used: 160 mmHg/21.33 kPa • Adults/children when SuperSTAT algorithm is used: 135 mmHg/18.00 kPa • Neonates, SuperSTAT algorithm: 100 mmHg/13.33 kPa Setting range for systolic target cuff pressure: • Adults/children: 100 to 250 mmHg (13.3 to 33.3 kPa) • Neonates: 70 to 140 mmHg (9.3 to 18.7 kPa)

SpO_2 setup

The third tab under Monitor Setup is ***SpO_2***. Menu selections for SpO_2 differ depending upon the technology (GE TruSignal, Nellcor, or Masimo) used. Refer to "GE TruSignal SpO2" on page 7-1, "Masimo SpO2" on page 8-1 or "Nellcor SpO2" on page 9-1 for technology-specific options.

More Nellcor, GE TruSignal and Masimo settings as well as alarm limits can be set in configuration mode. For all other setup issues, contact service.



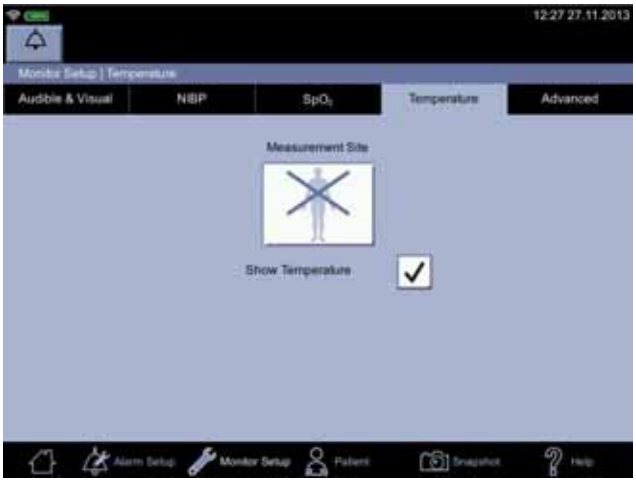


Masimo

SpO_2 screen options	Description
SpHb, RR, RRa, SpMet, SpCO, SpOC, PI	If checked, the option will be shown on screen. Availability of the options depends on the SpO_2 technology used.
Show Graph	If ***Waveforms*** is selected, the monitor will display a parameter waveform on screen.
Waveform parameters	Selection of SIQ or RRa (Masimo), or SpO_2 (TruSignal, Masimo and Nellcor) for waveform display. One, two or all of these can be displayed at the same time. Deselection of a waveform parameter removes it from the screen display.
Measurement Site	Selection for the part of the patient's body where SpO_2 sensor is located. 
Sensitivity Mode	Refer to "Masimo rainbow® SET® SpO2 configuration" on page 8-25 for more information on optional Masimo features available if licenses for these were purchased with the unit or afterwards.
FastSat	
SpO_2 Averaging Time	
RRa Averaging Time	

Temperature setup

The fourth tab under ***Monitor Setup*** is ***Temperature***. If the monitor is equipped with the Exergen temperature technology and ***Show Temperature*** check box is selected, the temperature parameter on the home screen is displayed and vice versa.



If the monitor is equipped with Welch Allyn temperature technology, the check box is disabled and the temperature parameter is always displayed on the home screen.

Temperature options	Description
Measurement Site	Selection for the part of the patient's body where temperature is measured. Availability of the sites depends on the temperature technology used. 
Show Temperature (Exergen only)	If checked, the temperature parameter is displayed on the screen.

Advanced

The fifth tab under ***Monitor Setup*** is ***Advanced***, which consists of three login boxes. Password-protected ***Default Setup*** is intended for someone at the hospital or care unit that has the training and authority to configure default settings for the monitor. Password-protected ***Service Mode*** is intended only for service personnel. ***Start Remote Service*** is activated by the nurse manager or the service and thereafter intended only for the service personnel.

Patient

Refer to "Patient and caregiver data" on page 5-1 for information on admitting or discharging a patient.

Patient identification

Before taking any measurements on a patient, identify the patient as instructed in "Selecting or adding a patient" on page 5-6. This helps avoid risk of assigning snapshots to the wrong patient. Patient identification can be done later as well, but you cannot send the snapshots to the hospital EMR before the patient is identified. If hospital policy requires a positive patient identification, refer to "Positive patient identification" on page 5-9.

Snapshot

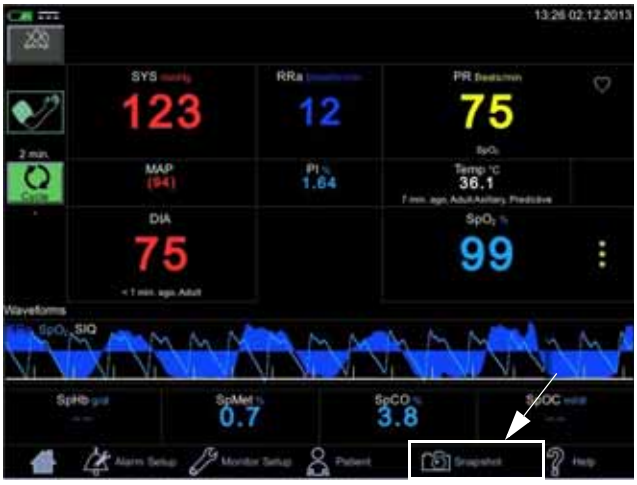
Vital signs data can be captured as a snapshot and stored in patient data. Some measurements are stored automatically. Refer to "Patient and caregiver data" on page 5-1 for more on snapshots. The monitor stores the snapshot in a list of patient data entries in ***Patient*** for viewing, printing or sending out to the EMR.

Select ***Snapshot*** to capture measurement values. When the values are captured, the background for screen values will turn gray for a short moment and two short beeps are signaled.

NOTE

NIBP values, Exergen values and Welch Allyn predictive measurement values are automatically stored in patient data when the measurement is complete. There is no need to select ***Snapshot*** for these values.

If you want to store all active measurement values when the NIBP measurement is complete, ask the nurse manager or service to select ***Snapshot upon NIBP completion*** in configuration mode.



Help

Selected sections of this operator's manual can be accessed in the Help menu. Select ***Help*** to access an index page where you can scroll through the content. You can use the ***Back*** and ***Forward*** keys to move between pages. Select ***Close*** to exit help.

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4 Alarms

Description

Physiological alarms are active only in monitoring mode, not in spot-check mode. Alarm condition notifications include:

- An LED light on the top of the monitor.
- An audible alarm signal (always with high or medium priority level alarms, can be enabled/disabled in configuration mode for low priority alarms).
- The parameter display is highlighted for the parameter causing the alarm (parameter value with priority color on the background).
- A note under the parameter value (technical conditions only). If the status of the measurement is abnormal, then white text indicating the issue will appear below the parameter value. If the abnormal state remains for 10 seconds, then a blue or yellow (low or medium priority) alarm is generated.
- Alarm message text displayed in the notification area at the top of the screen.

> WARNING
> Do not silence or disable audible alarms or decrease the volume of the audible alarm if patient safety could be compromised. Do not dim or disable visual alarms if patient safety could be compromised.

Alarm types

Physiological alarms

When a patient's vital signs are above an upper parameter limit or below a lower parameter limit, a physiological alarm is invoked. The monitor checks each derived vital sign (except temperature) against user-set limits. A high limit alarm is generated when a value exceeds a high limit. A low limit alarm is generated when a value is less than a low limit.

Technical alarms

When an electrical or mechanical failure of the equipment, loss of measurement data, or a sensor or component failure happens, a technical alarm is invoked in the notification area. Technical alarms may also be displayed when an algorithm cannot classify or interpret the available data.

Battery alarms

The monitor can display alarms for low charge, depleted battery or a battery problem. Refer to "Battery" on page 13-1 for more on battery operation. There are two alarms indicating that the battery is low.

- Low priority alarm ***Battery Low*** when there is power left for approximately 10 NIBP determinations.
- High-priority alarm ***Battery Low*** when there is power left for approximately 5 minutes of operation.

NOTE

When the battery is nearly depleted, the monitor displays a high priority alarm message in the notification area. Once this message appears on screen, there are 5 minutes of operation time left. NIBP measurement or printouts with the strip printer are not allowed anymore. Five minutes after the message appears, the monitor will terminate active operations and shut down.

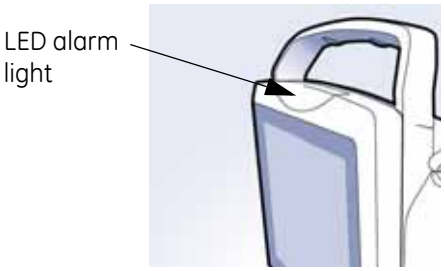
Alarm signals

The monitor provides visual and audible alarm signals when an alarm condition is present unless an alarm is silenced for 2 minutes with the silence icon. Other audible signals remain enabled. Refer to "Alarm silence indicator" on page 4-5.

Priority level	Highlight color	Description
HIGH	RED	Requires an immediate response.
MEDIUM	YELLOW	Requires a prompt response.
LOW	BLUE	Requires the user to be aware of this condition.
NOTIFICATION	GRAY	Provides additional information. No assigned priority. In some cases, the message is also shown as low priority text in the applicable parameter area.

NOTE

Selecting the silence icon does not acknowledge the alarm. It just silences the audible signal.



	Alarm type	Alarm priority color	LED	Message blinks on screen	Parameter field highlighted	Alarm sound[1]	Notification in parameter field	Escalation	Monitoring mode	Spot-check mode
1	Clinical[2]	Red	Yes	Yes	Yes	Yes	No	No	Enabled	Disabled
		Yellow	Yes	Yes	Yes	Yes	No	No		
		Blue	Yes	No	Yes	Yes[3]	No	No		
2	Technical	Yellow	Yes	Yes	No	Yes	No	No		Enabled
		Blue	Yes	No	No	Yes[3]	No	No ↑		
		Gray	No	No	No	Yes	Yes[4]	Yes[5] ↑		
3	System	Gray	No	No	No	Yes	No	No		
4	Battery	Red	Yes	Yes	No	Yes	No	No ↑		
		Blue	Yes	No	No	Yes[3]	No	Yes[5] ↑		

[1] For description of beeps, refer to the table in the Alarm tones section.
[2] Clinical alarms are not active in spot-check mode.
[3] Low priority alarm sounds can be silenced if required. Refer to "Alarm silence indicator" on page 4-5 for instructions.
[4] Some alarms.
[5] Refer to "Escalation of an alarm condition" on page 4-6.

When multiple alarm conditions occur at the same time, the monitor will sound an alarm tone for the highest priority alarm. Any lower priority alarm is superseded by the higher priority alarm. If the high priority alarm is cleared, but the lower priority alarm condition still remains, the monitor goes back to sounding the lower priority alarm.

NOTE

Alarm priorities can be adjusted in configuration mode.

Alarm tones

The high-pitched, continuous battery low shutdown alarm tone sounds cannot be silenced. Sounds related to low priority alarms can be silenced in configuration mode. Do not silence the alarm unless specifically requested by the care unit.

Priority	Sound	Beeps
High	Yes	10 beeps in series of 3-2-3-2, repeated every 15 sec.[1]
Medium	Yes	3 beeps every 15 seconds
Low	Yes (if enabled in Default Setup)	1 beep every 15 seconds
Technical	Yes	2 short beeps

[1] Alarm tone patterns repeat continuously until silenced, acknowledged or the condition causing the alarm is removed.

Alarm silence indicator

To silence an alarm (physiological or technical) at any time, select the silence icon. The alarm bell icon will turn red. When two minutes of silence expires, the alarm sounds again, unless the alarm condition has cleared out. If latching is selected, the alarm message will be displayed even though the alarm condition has cleared out. The message must be acknowledged.

The alarm silence indicator has two states:

- Red alarm bell: Alarm silence is active and the audible alarm tones are silenced for 2 minutes. A countdown timer underneath the indicator displays the remaining time for the silence.

- Off: Alarm silence is not active.

NOTE

In spot-check mode, this icon is replaced by the alarm off symbol.

Escalation of an alarm condition

Alarms may be escalated in some cases.

Alarm type	Level of escalation
Physiological alarms	None
Battery charge alarms	The monitor asserts a low priority alarm when the battery has enough power for approximately 10 NIBP determinations. The monitor asserts a high priority alarm when the battery has enough power for approximately 5 minutes of operation.
Technical notifications	The monitor escalates an abnormal technical status to a low priority alarm after 10 seconds.
System notifications	None

Flashing parameter numbers

With a high-priority clinical alarm, the parameter field lights up and the message in the notification area blinks to attract attention.

Remote alarms

A remote alarm activates when any medium or high priority alarm or system failure alarm is active, or if the monitor is powered off. The remote alarm signal tracks the state of alarms asserted locally at the monitor. Whenever an alarm is being sounded, the remote alarm is also asserted. Refer to "Connections" on page A-2 for additional information on the remote alarm.

When a medium or high priority alarm condition is displayed on the monitor, the remote alarm signal becomes active. The active state of the alarm signal is an open circuit. In the inactive state the alarm signal is connected to ground.

NOTES

The primary method of asserting alarms is always locally by the monitor itself. The remote alarm should only be considered a supplemental method of asserting alarms.

The monitor does not support Hostcomm 1846 communication protocol.

Acknowledging an alarm

The alarm message is acknowledged by selecting the message in the notification area on top of the screen. The error message disappears, but the parameter area will be highlighted as long as the error condition exists. Audible and visible alarms disappear automatically when an alarm condition no longer exists, unless latching is selected.

For a list of acknowledgeable alarms, refer to "Alarms and priorities" on page 4-7.

Alarms and priorities

The following tables list physiological and technical alarm conditions for the VC150 monitor. Messages are either alarms or informative ones.

Physiological alarm conditions

Alarm condition	Alarm limit range	Factory default limit	Factory default priority
NIBP Systolic High (adult/pediatric)	35 to 290	200 mmHg	Medium
NIBP Systolic High (neonates)	35 to 140	100 mmHg	
NIBP Systolic Low (adult/pediatric)	30 to 285	80 mmHg	
NIBP Systolic Low (neonates)	30 to 135	40 mmHg	
NIBP Diastolic High (adult/pediatric)	15 to 220	120 mmHg	
NIBP Diastolic High (neonates)	15 to 110	60 mmHg	
NIBP Diastolic Low (adult/pediatric)	10 to 215	30 mmHg	
NIBP Diastolic Low (neonates)	10 to 105	20 mmHg	
MAP high (adult)	25 to 260	Off[1]	Off[1]
MAP high (neonate)	25 to 125		
MAP low (adult)	20 to 255		
MAP low (neonate)	20 to 120		
SpO_2 High	71 to 99	Off	Medium
SpO_2 Low	70 to 98	90%	
Pulse Rate High	35 to 235	150 beats per minute	Low
Pulse Rate Low	30 to 230	50 beats per minute	
Perfusion Index High	GE TruSignal: 0.3 to 31.8% Masimo and Nellcor: 0.3 to 19.0%	Off	Off
Perfusion Index Low	GE TruSignal: 0.2 to 31.7% Masimo and Nellcor: 0.2 to 18.0%		

Alarm condition	Alarm limit range	Factory default limit	Factory default priority
Acoustic Respiration Rate High[2] (Masimo)	5 to 69	30 breaths per minute	Medium
Acoustic Respiration Rate Low[2] (Masimo)	4 to 68	6 breaths per minute	
Acoustic Respiration Rate Timeout[2]	0, 1, 5, 10 or 15 minutes	5 minutes	
Respiration Rate High[2] (Nellcor)	5 to 40	30 breaths per minute	
Respiration Rate Low[2] (Nellcor)	4 to 39	6 breaths per minute	
Saturation Pattern Detection, SPD[2]	Off/Most sensitive/ Moderately/Least	Off	
SpMet High[2] (Masimo)	1.0 to 99.5	3.0	
SpMet Low[2] (Masimo)	0.2 to 99.0	Off	
SpCO High[2] (Masimo)	2.0 to 98.0	10.0	
SpCO Low[2] (Masimo)	1.0 to 97.0	Off	
SpHb High[2] (Masimo)	2.0 - 24.5 g/dl or 2.0 - 15.0 mmol/l	17.0 g/dl or 11.0 mmol/l	Low
SpHb Low[2] (Masimo)	1.0 - 23.5 g/dl or 1.0 - 14.5 mmol/l	7.0 g/dl or 4.0 mmol/l	
SpOC High[2] (Masimo)	2.0 - 34.0 mL O_2/dl blood	25.0 O_2/dl blood	
SpOC Low[2] (Masimo)	1.0 - 33.0 O_2/dl blood	10.0 O_2/dl blood	
3D Desaturation Index	Multiple selectable settings, please see SpO_2 section for Masimo	-	Off
3D Perfusion Index Delta			

[1] MAP alarm can be enabled in ***Default Setup > Alarm Defaults***
[2] Licensed feature, availability depends on the OEM measurement module hardware.

To change alarm default settings, refer to "Alarm defaults" on page 14-4.

Technical alarm conditions

Technical alarm conditions	
Message in the notification area	Possible cause/description/action
Battery messages	
Battery Low	• When a low priority alarm, this indicates that there is enough power left for approximately 10 NIBP measurements. • When a high-priority alarm, this indicates that the monitor will stop all processes and shut down after approximately 5 minutes after this alarm. NIBP measurements and printing are disabled from now on.
Host software messages	
Audio not available	• Audio cannot be played by the speaker inside the monitor case. Potential hardware problem. • Contact service.
Battery not connected	• Please contact service. • Displayed as a full screen message when battery is removed or broken. Contact service.
Cannot connect to remote server	• Authentication of patient data query failed due to connection error to remote host. • Authentication of the caregiver ID failed due to connection error to remote host. • Contact service.
Caregiver authentication failed	• Authentication of the caregiver failed due to wrong password or unknown username. • Enter the username and password and try again to authenticate.
Caregiver ID requires validation	• Validated caregiver ID is required to send a record to EMR, but the caregiver ID is not validated. • Caregiver authentication is required to make a patient demographics query.
Caregiver ID required	• An attempt was made to send an EMR record without a valid caregiver ID. • Provide a valid caregiver ID.
Failed to update time	• System time not received from the NTP server. Potential network error. • Contact service.

Technical alarm conditions	
Message in the notification area	Possible cause/description/action
Internal Bus Communication Failure Please contact Service	• Internal problem. Contact service. If the problem persists, do not use the monitor.
Invalid EMR Encoding	• Hospital-specific EMR settings are not valid. • Contact service.
Invalid Identification	• Incorrect ID due to missing or incomplete ID or missing password. • Enter the identification and the password again.
Invalid SSL configuration	• Authentication of a patient data query failed due to SSL error. • Authentication of the caregiver ID failed due to SSL error. • Contact service.
Local History Reset	• Local history database is reset.
Local History Unavailable	• Storage of patient data to local history database failed. Storage space may be full. • Contact service.
Local History Unit Error	• Storage of physiological measurement to the local history database failed due to changed unit of measurement. Only one unit per type of measurement is allowed in the database. • Delete patient history as instructed in "Deleting patient history" on page 5-21. When this is done, restart measurements.
Patient ID requires validation	• Validated patient ID is required to send a record to EMR, but the patient ID is not validated.
Patient ID required	• An attempt was made to send a record to EMR without a valid patient ID.
Patient will be discharged if time is changed	• The user is about to change the system time. • The user is informed that a patient will be discharged if the system time is changed.
PM in N days	• Preventive maintenance date will pass after N days (where N = the number of days). • Contact service.

Technical alarm conditions	
Message in the notification area	Possible cause/description/action
PM passed N days ago	• Preventive maintenance date passed N days ago (where N = the number of days). • Contact service.
Printer error	• Check the battery charge level. • If the problem persists, contact service.
Printer out of paper	• Insert paper to the printer.
Printer temperature	• Let the printer cool down. If the problem persists, contact service.
Send to EMR failed	• Failure to send a record to the EMR due to a network or other error. • Contact service.
Settings changed	• Service has performed remote management work on the monitor.
Storage 100% full	• Permanent storage partition volume is full. • Contact service.
Storage 75% full	• Permanent storage partition volume is nearly full.
Storage 90% full	• Permanent storage partition volume is nearly full. • Contact service.
System crash detected	• The system did not shut down correctly before the latest restart.
USB not available	• Restart the monitor. If the problem persists, contact service.
USB <port number> overcurrent	• Connected USB device does not operate as it is drawing excess amount of power. Contact service.

Exergen messages		
Message in the notification area	Possible cause/ description	Action
Temp Battery Low	• Battery low error	• Replace the battery.
Temp Battery Empty	• Battery fatal error	
Temp Measurement Too High	• Target temperature too high	• Check patient condition.
Temp Measurement Too Low	• Target temperature too low	
Temp Ambient high	• High ambient temperature	• Cool down the ambient room temperature.
Temp Ambient low	• Low ambient temperature	• Warm up the ambient room temperature.

These messages are also shown under temperature value.

The scanner may also display additional indicators on the scanner's LED window.

LED window	Condition	Description/Action
HI	Temperature too high	> 43° C (110° F)
LO	Temperature too low	< 16° C (61° F)
HI A	High ambient temperature	> 40° C (104° F)
LO A	Low ambient temperature	< 16° C (61° F)
bAtt	Low battery	Replace battery soon.

LED window	Condition	Description/Action
(blank display)	Dead battery	Replace battery.
Err	Processing error	Unplug and plug the scanner into the monitor. Contact Innokas Medical or Innokas Medical representative.

Masimo messages		
Message in the notification area	Possible cause/description	Action
Respiration Pause	• A pause in respiration has been detected.	• Check the patient. • Adjust the sensor.
RRa Faulty Probe	• Defective sensor/ adhesive sensor	• Replace sensor.
RRa Incompatible Cable	• Incompatible cable	• Use the proper Masimo cable. • Replace cable.
RRa Incompatible sensor	• Incompatible sensor/ adhesive sensor	• Replace sensor.
RRa Interference detected	• Noise by moving patient impedes measurement • Ambient noise impedes measurement	• Ask the patient remain still. • Check for sources of ambient noise.
RRa No Cable Connected	• No cable connected • Defective cable	• Disconnect and reconnect cables. • Replace cable.
RRa No Sensor Connected	• No sensor/adhesive sensor connected	• Disconnect and reconnect cables. • Replace sensor.
RRa Not Available	• SpO_2 module malfunction	• Contact service.
RRa Replace Cable	• Cable life has expired • Unrecognized cable • Defective cable • Sensor cable fault	• Replace cable.

Masimo messages		
Message in the notification area	Possible cause/description	Action
RRa Replace Sensor	• Adhesive or reusable sensor life has expired • Unrecognized sensor	• Replace sensor.
RRa Sensor Off Patient	• Sensor is off patient	• Apply sensor at the appropriate location or adjust the sensor.
SpO_2 - SpO_2 Only Mode	• SpO_2 only mode	• Apply sensor at the appropriate location or adjust the sensor.
SpO_2 Demo mode	• Demo mode	• Contact service.
SpO_2 Faulty Cable	• Defective cable • Sensor cable fault	• Replace cable.
SpO_2 Faulty Probe	• Defective sensor • Unrecognized adhesive sensor	• Replace sensor.
SpO_2 Incompatible Cable	• Incompatible cable	• Use proper Masimo cable. • Replace cable.
SpO_2 Incompatible Sensor	• Incompatible sensor	• Replace sensor.
SpO_2 Interference Detected	• Nail polish • Sensor too tight • Incorrect sensor position • Excess infrared light or bright ambient lights • Electrical/optical interference • Excessive ambient temperature	• Remove nail polish. • Loosen the sensor a little. • Reposition the sensor. • Remove source of infrared light. • Adjust ambient lighting. • Clean sensor site. • Cool down the site.
SpO_2 No Cable Connected	• No cable connected	• Connect cable. • Disconnect and reconnect cables.

Masimo messages		
Message in the notification area	Possible cause/description	Action
SpO_2 No Sensor Connected	• No sensor/adhesive sensor connected	• Disconnect and reconnect cables. • Replace sensor.
SpHb Not Available	• The selected sensor is not capable of measuring SpHb. The SpHb sensor life is expired. • SpHb parameter selected for display.	• Select a sensor capable of measuring SpHb. • Replace the sensor. • Deselect SpHb in the Monitor Setup, if you do not want to use this sensor. If SpHb is never used, ask the nurse manager or service to deselect SbHb in configuration mode.
SpO_2 Perfusion Low	• Low perfusion index • Signal too weak	• Check the patient. • Adjust the sensor. • Move the sensor to another site with better perfusion. • Refer to "Masimo low perfusion" on page 8-44.
SpO_2 Pulse Search	• Pulse cannot be determined	• Check the patient. • Adjust the sensor.
SpO_2 Replace Cable	• Cable life has expired • Unrecognized cable • Defective cable	• Replace cable.
SpO_2 Replace Sensor	• Sensor/adhesive sensor life has expired • Defective adhesive or reusable sensor • Unrecognized sensor	• Replace sensor.
SpO_2 Sensor Off Patient	• Sensor is off patient	• Apply sensor at the appropriate location or adjust the sensor.

Masimo messages		
Message in the notification area	Possible cause/description	Action
Time remaining on SpHb sensor	• Displays the remaining lifetime of the SpHb sensor.	• No action required.
Masimo Informative messages		
SpO_2 Not Available or *SpO_2 Programming Failed* or *SpO_2 Invalid system app*	• SpO_2 module malfunction	• For *$Sp0_2$ Not Available*: Restart the monitor. If the problem persists, contact service. • For other messages, contact service.

Nellcor messages		
Message in the notification area	Possible cause/description	Action
SpO_2 Faulty probe	• Defective sensor • Unrecognized sensor	• Replace sensor.
SpO_2 Interference Detected	• Nail polish • Sensor too tight • Incorrect sensor position • Excess infrared light or bright ambient lights • Electrical/optical interference	• Remove nail polish. • Loosen the sensor a little. • Reposition the sensor. • Remove source of infrared light. Adjust ambient lighting. • Clean sensor site.
SpO_2 No Sensor Connected	• Sensor disconnected	• Check all connections. If the problem persists, replace the cable and/or the sensor.
SpO_2 Not Available	• SpO_2 module malfunction	• Contact service.

Nellcor messages		
Message in the notification area	Possible cause/description	Action
SpO_2 Pulse Search	• Waiting for the algorithm to provide a valid SpO_2 value. • A low priority ***SpO_2 Pulse search*** alarm indicates that the data update period has exceeded 30 seconds.	• Reposition the sensor. Replace the sensor if the problem persists.
SpO_2 Sensor Off Patient	• Sensor not attached to patient	• Reposition the sensor. If the problem persists, replace the cable and/or the sensor.
SpO_2 Pulse Timeout (Nellcor)	• Sensor connected to a patient AND detected a pulse in the past AND now is unable to determine the pulse rate value or oxygen saturation. This condition will trigger a high-priority alarm.	• Check the patient immediately. • Reposition or replace the sensor.

NIBP messages		
Message in the notification area	Possible cause/description	Action
NIBP Status and result messages		
NIBP Level Timeout	• Maximum allowed time of 1 minute reached for a single cuff pressure.	• Check patient condition, limit patient movement. • Check for proper size cuff. • Reapply cuff. • Check hose and cuff tubing for kinks or tangles. • Check cuff position. • Restart NIBP unless a specific reason not to restart exists.
NIBP Not Available	• NIBP module malfunction	• Contact service.
NIBP No Determination	• Determination failed (no complexes) • Maximum allowed time reached for a single determination.	• Check patient condition. • Check for proper size cuff. • Check cuff position. • Reapply cuff. • Check hose and cuff tubing for kinks or tangles. • Restart NIBP unless a specific reason not to restart exists.
NIBP Overpressure	• Excessive cuff pressure • Pressure too great between determinations	• Excessive cuff pressure. Check for hose blockage. • Check hose and cuff tubing for kinks or tangles. • Restart NIBP unless a specific reason not to restart exists. • If the problem persists, contact service.

NIBP messages		
Message in the notification area	Possible cause/description	Action
NIBP Pneumatic leak	• Inflation timeout due to pressure leak	• Check or replace hose or cuff. • Check connections for all hose and cuff fittings. • Restart NIBP unless a specific reason not to restart exists. • If the problem persists, contact service.
NIBP Total Timeout	• Length of determination has exceeded 2 minutes for an adult/pediatric, or 85 seconds for a neonatal determination.	• Check patient condition, limit movement. • Check target inflation pressure. • Reapply cuff. • Check hose and cuff tubing for kinks or tangles. • Check cuff position. • Restart NIBP unless a specific reason not to restart exists.
NIBP Unable to zero	• Pressure too high between measurements. Determination cannot be made due to residual pressure in the cuff.	• Check that the hose is not tangled or kinked. • Restart NIBP unless a specific reason not to restart exists. • If the problem persists, contact service.

GE TruSignal messages		
Message in the notification area	Possible cause/description	Action
SpO_2 Bad Placement	• Incorrect sensor placement	• Loosen the sensor a little. • Reposition the sensor. • Reboot the monitor.
SpO_2 Faulty Probe	• Sensor failure	• Reboot the monitor. • Replace with correct sensor type.
SpO_2 Low signal quality	• Nail polish • Sensor too tight • Incorrect sensor position • Excess infrared light or bright ambient lights • Electrical/optical interference	• Remove nail polish. • Loosen the sensor a little. • Reposition the sensor. • Remove source of infrared light. Adjust ambient lighting. • Clean sensor site.
SpO_2 No Sensor Connected	• Sensor disconnected	• Check the cable. Plug in properly.
SpO_2 Not Available	• SpO_2 module malfunction	• Contact service.
SpO_2 Pulse Search	• Waiting for the algorithm to provide a valid SpO_2 value.	• Reposition the sensor. Replace the sensor if the problem persists.
SpO_2 Sensor Off Patient	• Sensor status is off.	• Reposition the sensor. Replace the sensor if the problem persists.

Welch Allyn SureTemp® Plus (WA) messages		
Message in the notification area	Possible cause/description	Action
Temp Ambient High	• Ambient temperature too high	• Move the monitor to a place with lower ambient temperature. If the problem still persists, contact service.
Temp Ambient Low	• Ambient temperature too low	• Move the monitor to a place with higher ambient temperature. If the problem still persists, contact service.
Temp Faulty Probe	• Probe malfunction	• Contact service.
Temp Interference Detected	• Measurement below allowable patient or ambient temperature • Temperature module malfunction	• Check patient temperature manually. If patient temperature is normal and the problem still persists, contact service.
Temp Measurement Too High	• Target temperature too high.	• Check patient condition.
Temp Measurement Too Low	• Target temperature too low.	• Check patient condition.
Temp No Sensor Connected	• Probe detached	• Attach the probe again. If the problem persists, contact service.
Temp Not Available	• Temperature module malfunction	• Contact service.
Temp No Determination	• A predictive measurement could not be completed.	• Select the snail icon to start monitor mode and to display real-time measurement data.

Welch Allyn SureTemp® Plus (WA) messages		
Message in the notification area	Possible cause/description	Action
Temp Probe Too Hot	• Probe temperature above 43.3° C (110° F).	• Check patient temperature manually. If patient temperature is normal and the problem still persists, correct probe tip conditions. • If the problem persists, replace probe. • If the problem still persists, contact service.
Temp Probe Well Missing	• Probe well missing or not installed properly.	• Re-insert probe well or check for alignment problem. • Contact service.
Temp Replace Sensor	• Probe malfunction.	• Re-attach probe well, If the problem still persists, contact service.
Temp Sensor Off Patient	• Temperature probe not on the patient	• Reposition the sensor.

Alarm specifications

Alarm volume	40 dB to 90 dB.
Alarm delays and remote alarm	There is no discernible delay in alarms due to electronics or software algorithms. All priority alarms are triggered immediately unless a delay has been configured. Refer to SpO_2 section for different types of alarm delays available depending on SpO_2 technology. All medium and high-priority alarms are asserted to the remote alarm interface within 0.5 sec unless alarms are silenced for the two-minute period. Information messages for various technical fault conditions are displayed immediately near the relevant parameter value or in the information area. A low priority alarm is triggered in 10 seconds if the technical fault persists.
Remote alarm sound	Remote alarm does not have sound.

Factory default settings for alarm limits

Refer to "Alarms and priorities" on page 4-7 for a listing of factory defaults for alarm limits.

Logs

All alarm conditions are stored in productivity metrics log. The productivity metrics log is also used to record the following:

- Changes in alarm limit and priority settings.
- Alarm condition that has become active.
- Priority of the alarm.
- Alarm condition that has ceased.

The log file is stored in a permanent memory that survives power loss and removal of the battery. The log is accessible to the service user.

All technical alarm conditions are stored in error log, which is accessible to the service user.

5 Patient and caregiver data

Description

The ***Patient*** screen allows you to access stored patient data. Retrieving snapshot points is especially useful when doing hospital rounds: if the patient's temperature and SpO_2 measurements are taken while an NIBP determination is in progress, then upon completion of the determination, the vital signs for a patient can be analyzed on screen or printed out.

The following information refers to operation in clinical mode. The monitor can hold 3000 stored entries in history. It displays the most recent entries first. Entries are automatically removed when they become older than 24 hours if these are not printed to a PDF or queued up for sending to the EMR.

The patient data is maintained and displayed in the ***Patient*** screen with a time stamp at the top of the snapshot. Missing parameter data leaves an empty column in the table. Admitting a new patient also creates an empty column. A new snapshot is added to the left side of the table.

An entry is stored in local clinical history at the completion of an NIBP determination and at the completion of an Exergen temperature measurement or a successful predictive Welch Allyn temperature measurement. At the end of an NIBP determination, systolic, diastolic, MAP and PR values are stored.

NOTES

When SpO_2 is being monitored continuously, values are only stored when the snapshot icon is selected. Predictive temperature values are stored separately after each determination. If ***Snapshot upon NIBP completion*** has been selected in configuration mode, then current SpO_2 value is stored when NIBP measurement is complete.

Only those items that are selected to display on the screen are stored in the snapshot. Visible screen items can be adjusted in the related parameter tab in ***Monitor Setup***.

CAUTION

If you need to use another unit of measurement for NIBP, first send all important patient data to the hospital EMR and then ask service to change the unit of measurement.

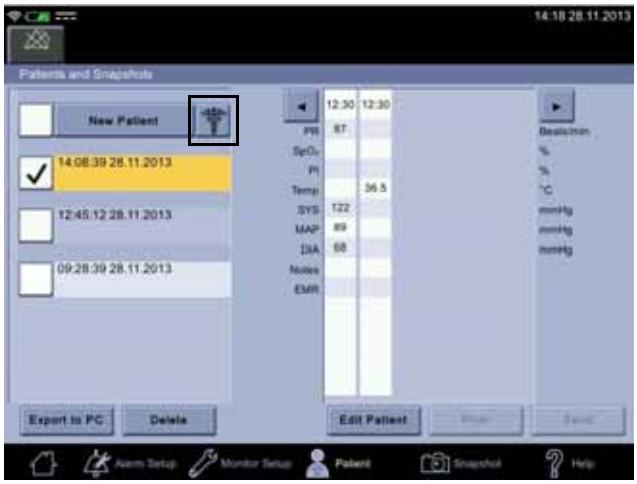
Adding a caregiver

Depending on hospital policy, the caregiver name might be used although it has not been identified. If the hospital policy requires validation of the caregiver identification, it is possible only if a WLAN connection to the hospital network has been set up and LDAP (Lightweight Directory Access Protocol) is configured correctly by service personnel.

Depending on country-specific laws of personal identity protection, the hospital IT system may return different search results. Still, the main purpose of the search is to confirm the identity of a caregiver or connect a patient to a correct identity. The following sections explain how to provide identification and positive caregiver or patient identification. If the caregiver name is not provided, but the ID has been validated by LDAP, the ID will be displayed as the caregiver.

Providing identification

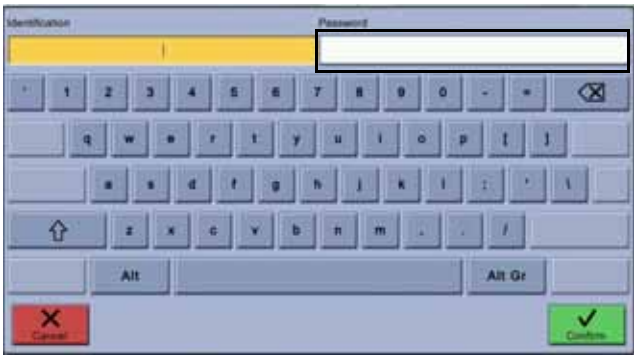
1. Select caregiver button to access ***Caregiver Info***. If you want to scan ID barcode, refer to "Using a barcode reader for caregiver ID" on page 5-5.



2. If another caregiver is logged on, select ***Log Off Caregiver***.

3. Select ***Name*** and enter your name.

4. Select ***Identification*** and enter your ID and password.



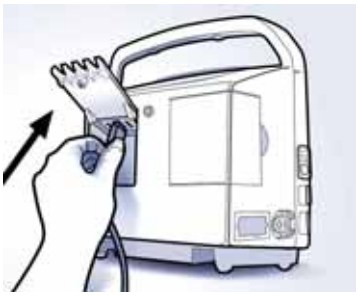
5. Select ***Confirm*** to confirm the entry or ***Cancel*** to cancel the selection.
6. Select ***Login*** to validate the login credentials.

7. If the ID was validated by the LDAP, the identification turns to gray.
8. If the identification was not validated and this is required by the hospital policy, re-enter the identification and the password and select ***Confirm***.
9. If a wrong identification was confirmed, select ***Log off Caregiver*** to discharge the previous caregiver and start the caregiver identification process again.

Using a barcode reader for caregiver ID

Caregiver identity can be verified by scanning the ID badge or entering the username and then providing a password.

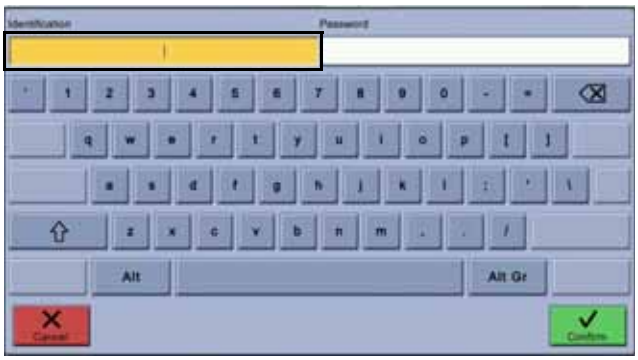
1. Check that a barcode reader is plugged in.



2. Select ***Patient***.

3. Select the caregiver icon.
4. Select ***Identification***.

5. Select ***Identification***.



6. Read the barcode.

7. Enter your password.

8. Select ***Confirm*** to confirm the entry or ***Cancel*** to cancel the selection.
9. Select ***Login*** to validate the login credentials.

10. If the ID was validated by the hospital LDAP, the identification turns to gray.
11. If the identification was not validated and this is required by the hospital policy, re-enter the identification and the password and select ***Confirm***.
12. If a wrong identification was confirmed, select ***Log off Caregiver*** to discharge the previous caregiver and start the caregiver identification process again.

Selecting or adding a patient

The patient ID can be entered manually or scanned with a barcode reader. Adding a new patient will discharge the current patient.

1. If you want to use a barcode reader to admit a patient, first refer to "Using a barcode reader for patient ID" on page 5-8, then proceed to step 5 on this list. Otherwise continue to step 2.

2. Select ***Patient > New Patient***.

3. Select ***Name.***

4. Enter name and then select ***Search*** to look for the patient in the HIS.

NOTES

If WLAN and ADT (admission, discharge & transfer)/PDQ (patient demographics query) are configured correctly by service, the ***Search*** icon is enabled and you can search for the patient in the HIS.

Information fields returned by the HIS (hospital information system) may vary depending on local laws and hospital policy.

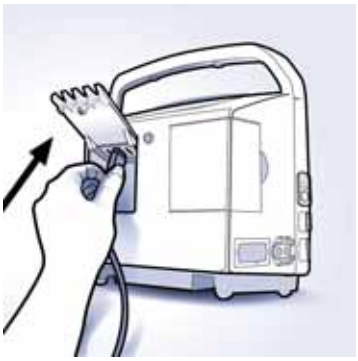
The ***Search*** icon is also disabled if the hospital policy requires caregiver authentication and this has not been done (refer to Providing identification). You can still enter the patient information and admit a new patient.

5. Proceed to "Positive patient identification" on page 5-9.

Using a barcode reader for patient ID

The patient identity can be provided by scanning the barcode on the patient's wristband. The barcode will be automatically read and placed in the patient ***Identification*** field, if service has enabled the ***Barcode shortcut*** feature. The shortcut can be used at any screen, except when text input field or any pop-up is active.

1. Check that a barcode reader is plugged in.



2. Scan the barcode on the patient's wrist band with the barcode reader while the monitor is e,g, on the home screen. After scanning, the monitor will launch the ***Patient info*** screen and fill in the patient ID into required field.
3. Proceed to step 5 of "Selecting or adding a patient" on page 5-6.

Positive patient identification

1. When the search returns a name, ask the patient for his/her name or date of birth. If the information about the new patient matches what the patient has said, select ***Confirm***.
2. If the search returned a wrong name, select ***Cancel*** and proceed to "Selecting or adding a patient" on page 5-6.
3. If a wrong patient was confirmed, select ***Edit patient***.

4. Edit patient data and select *Confirm*.

Snapshots

Obtaining vital signs snapshots for a patient

1. Perform measurements on a patient as instructed for each measurement.
2. Some snapshots are created automatically for measurements that have a clear end point. For measurements in process, select ***Snapshot*** to create a snapshot. All data is stored in a snapshot if ***Snapshot upon NIBP completion*** is enabled in configuration mode and temperature is in monitor mode.

<table>
<tr><th>Measurement</th><th>Source</th><th>Capture</th></tr>
<tr><td>NIBP</td><td>NIBP</td><td>Automatic</td></tr>
<tr><td rowspan="2">Temperature</td><td rowspan="2">Welch Allyn</td><td>Automatic
(when predictive mode is used)</td></tr>
<tr><td>Manual
(when monitor mode is used, animated snail icon on screen)</td></tr>
<tr><td rowspan="2">Pulse</td><td>Exergen</td><td rowspan="2">Automatic</td></tr>
<tr><td>NIBP</td></tr>
<tr><td rowspan="2">SpO_2</td><td>SpO_2</td><td rowspan="15">Manual
or
Automatic
(if enabled in ***Snapshot upon NIBP completion***)</td></tr>
<tr><td>GE TruSignal</td></tr>
<tr><td>PI</td><td>SpO_2</td></tr>
<tr><td>SpO_2</td><td rowspan="2">Nellcor</td></tr>
<tr><td>Respiration</td></tr>
<tr><td>SpO_2</td><td rowspan="6">Masimo</td></tr>
<tr><td>Respiration</td></tr>
<tr><td>SpMet</td></tr>
<tr><td>SpCO</td></tr>
<tr><td>SpHb</td></tr>
<tr><td>SpOC</td></tr>
</table>

NOTES

If the ***Snapshot*** icon was selected before any SpO_2 monitoring data was available, SpO_2 and pulse rate cells will be empty. The cells will also be empty if there is no measurement data available.

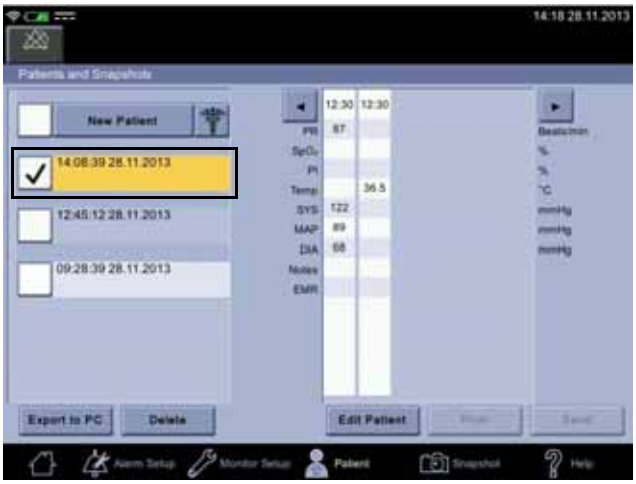
If a patient is being measured for over an hour, the patient data will be split into one-hour intervals. This also happens if the number of snapshots exceed 50. Different patients are separated by name.

You can scroll the snapshots back and forth with left and right arrows next to the snapshot list. The page count displays the current set of snapshots.

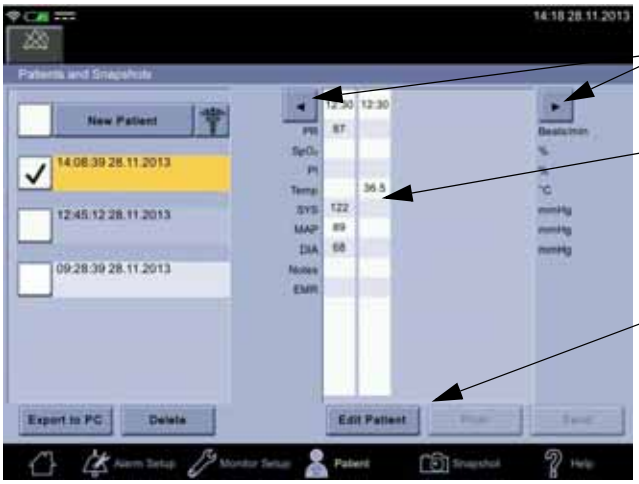
3. If you want to add notes on the patient's condition, refer to "Notes" on page 5-12.
4. Repeat measurements if more snapshots are required.
5. When examination is complete, remove the cuff and sensor.

Viewing snapshots

1. Select ***Patient***.
2. Select the patient whose snapshots you want to view. The selected patient will turn orange.



3. Select a snapshot you want to view. Scroll to the snapshot with arrows or with the scroll bar.



NOTE

If recent snapshots were taken without patient identification:

1. Select ***New Patient***. Add patient as instructed in "Selecting or adding a patient" on page 5-6.

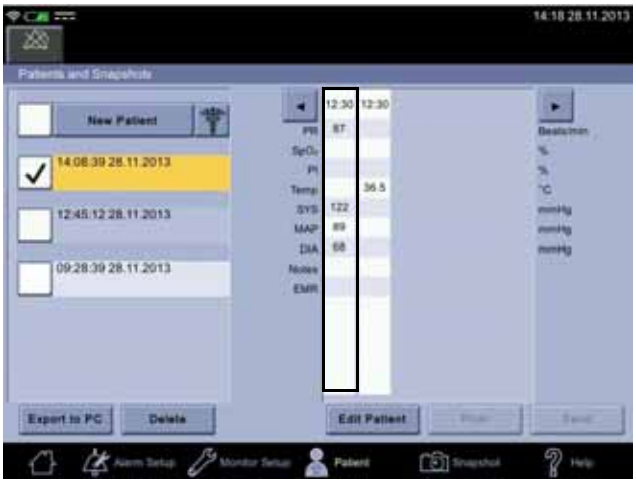
2. Select ***Confirm*** to return to the snapshot screen. Now the snapshots are assigned to the newly identified patient.

Notes

You can add additional information about the patient's condition, such as ***Pain Score***, ***Respiration Rate***, ***Consciousness***, ***Input*** and ***Output***. In addition to these, service can customize five additional fields for notes.

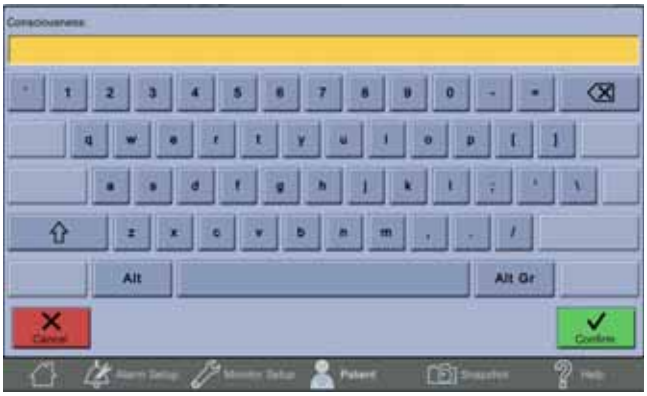
Adding notes

1. Select ***Patient***.
2. Select a snapshot to which you want to add a note.



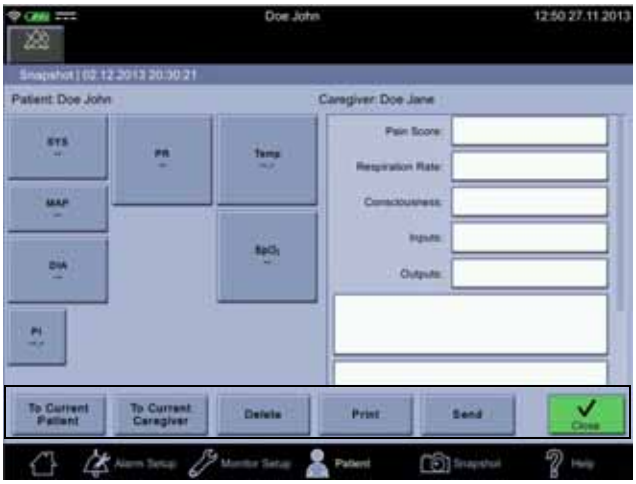
3. Select a note to which you want to add text.

4. Enter the information.



5. Select ***Confirm.***
6. Repeat steps 2 to 4 to add more notes.
7. When you are ready with the notes, select:

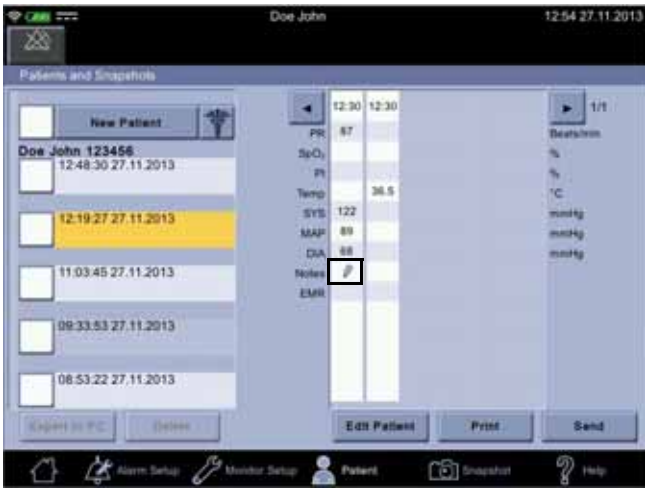
- ***To Current Patient*** to assign the snapshot to a current patient.
- ***To Current Caregiver*** to assign the snapshot to a current patient.
- ***Delete*** to delete the snapshot.
- ***Print*** to print the snapshot with the monitor strip printer.
- ***Send*** to send the notes to the hospital EMR via wireless connection. ***Send*** is available only if a WLAN connection and EMR are configured.
- ***Close*** to return to the ***Patients and Snapshots*** screen.



NOTES

Export to PC, ***Delete***, ***Print*** and ***Send*** buttons are disabled if the selected patient does not have any snapshots.

If you sent the snapshot with the notes, then select ***Close***. A pencil image at the intersection of the snapshot column and ***Notes*** row indicates there is something in the ***Notes*** area.



NOTE

Service can configure the monitor to delete a snapshot after records have been sent out.

Snapshot output

All or selected patient data can be printed, saved to a PDF, exported to USB as a PDF or transferred to the hospital EMR.

1. Select the patient as instructed in "Selecting or adding a patient" on page 5-6.
2. Select the patient interval.
3. Select the output type. Read further instructions below before you make a selection.

- ***Export to PC***. A PDF file for the selected interval is created and sent to a PC through USB. Service can set the PDF paper size as A4 or Letter.
- ***Delete***. The selected interval is deleted.
- ***Edit Patient***. Patient and caregiver information can be edited.
- ***Print***. The selected patient intervals are sent to the monitor printer.
- ***Send***. The selected intervals are sent to the hospital EMR if the patient has been identified. Also, the WLAN connection must be set up and the EMR destination configured by service. Name of the responsible caregiver is marked in all sent snapshots.

Export to PDF

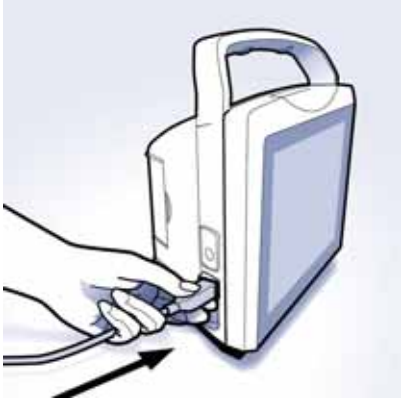
WARNING

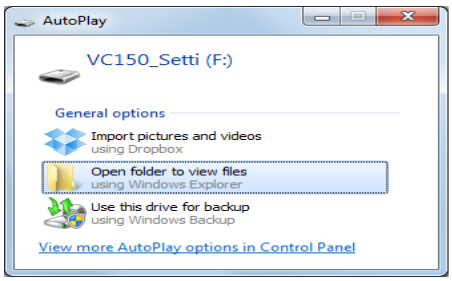
Electromagnetic interference from a desktop or a laptop computer connected to the VC150 may affect the performance of the monitor. Do not use the monitor for vital signs measurements while connected to a PC or laptop via USB-B connection.

1. Plug in a USB-B cable to a USB-B slot on the left side of the monitor and to the USB-A slot on a PC or Macintosh. The monitor looks like an external device on the file management system of the PC or Macintosh.

NOTE

The operating system of the PC or Macintosh must be new enough to support USB plug and play.





2. Select a patient interval. The monitor will mark snapshots with all available values in the selected interval of the patient data.

3. Select *Export to PC*. The monitor starts to a create a PDF out of marked snapshots. Do not print more than 1000 snapshots for a selected period. Save the PDF to a PC before printing more snapshots than that.

4. When the monitor has completed creation of the PDF files, you will see a following note on the screen. The PDF files can now be copied from the root directory onto the PC or MAC.

5. When you have copied the files, export more files or eject the USB device.
6. Unplug the USB.
7. Confirm the file export to exit the screen.

Print

Printed content vary depending on which SpO_2 and temperature technology is used to provide the data. A time stamp will be printed at the top of each snapshot. Column cells of a snapshot may be empty if values are not available or invalid. To tear off the printout, use a slight sideways action to pull the paper sharply up across the edge of the door.

Send

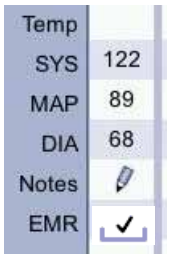
If the wireless network connection has been set up and the vital signs measurements for the case in question are associated with a patient identity, the ***Send*** icon is active. If the transfer was successful and deletion of sent records is enabled, the transferred snapshots will be removed from the screen. If the transfer was unsuccessful, then snapshots will turn gray and a gray technical message about a missing connection is displayed. The monitor will send the gray snapshots when the transfer becomes possible again.

NOTE

If you delete the patient, the monitor will ask for confirmation and checks also whether you want to delete also the unsent data. Deleting the current patient will discharge the patient.

Automatic snapshot deletion

By default, the monitor automatically deletes snapshot(s) after successfully transfer to the EMR. If you want to disable this, ask service to change the setting. An icon on snapshot cell indicates the status of the sending process of the snapshot. If ***Delete Sent Records*** has been enabled by service, the selected snapshot will disappear from the screen after successful transfer to the EMR.

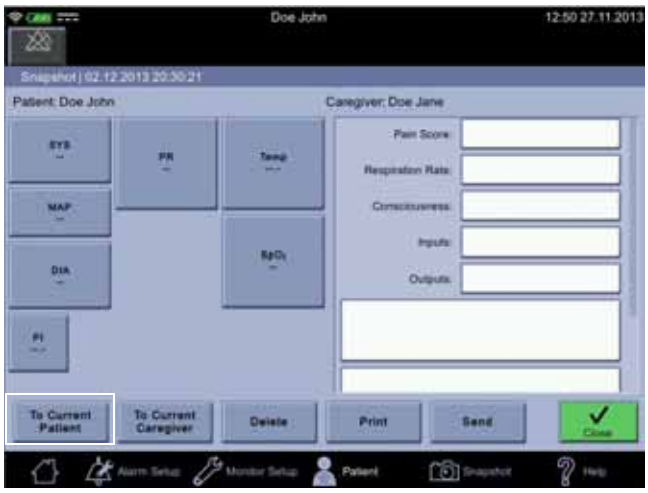


	Preparing to send
	Sending
	Sending failed
	EMR sent to the HIS

Assigning snapshots to a patient

1. Select ***Patient***.
2. Select a patient as instructed in "Selecting or adding a patient" on page 5-6. Then select ***Confirm*** to return to the snapshot screen.
3. Select a snapshot.

4. Select ***To Current Patient***.

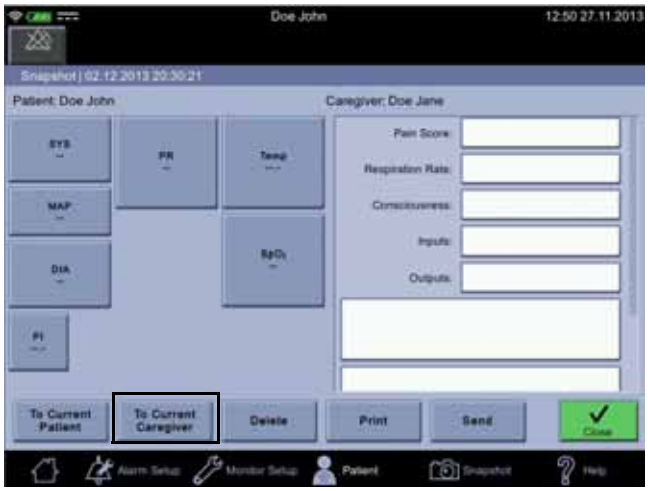


5. Select ***Close***.

Assigning snapshots to a caregiver

1. Select patient as instructed in "Adding a caregiver" on page 5-3. Then select *Close* to return to snapshot screen.
2. Select one snapshot.

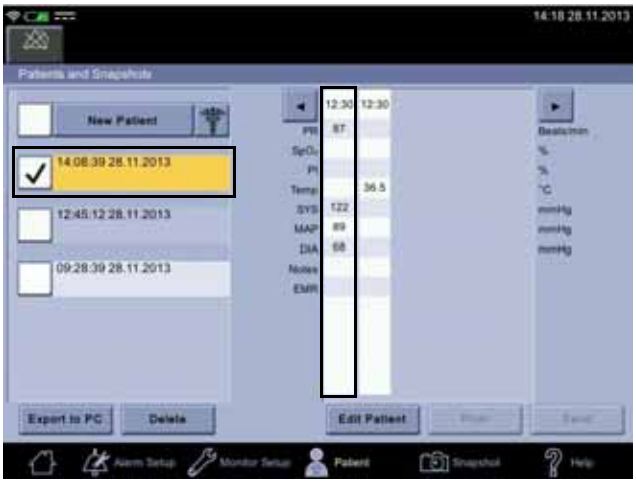
3. Select *To Current Caregiver*.



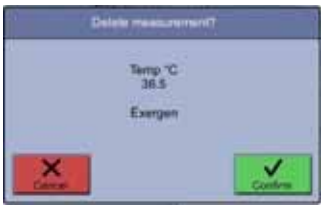
4. Select *Close*.

Deleting snapshot and notes

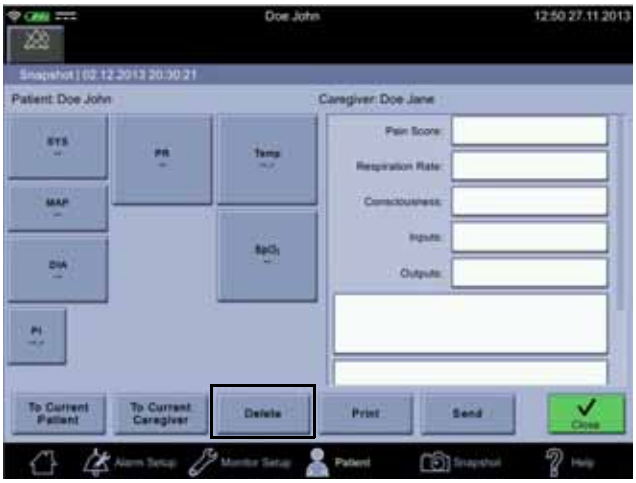
1. Select a patient as instructed in "Selecting or adding a patient" on page 5-6.
2. Select a snapshot.



3. If you want to delete a single measurements within a snapshot, select the measurement.
4. Select ***Confirm*** to delete the measurement or ***Cancel*** to exit the screen.



5. If you want to delete the snapshot with all measurements, select ***Delete***.



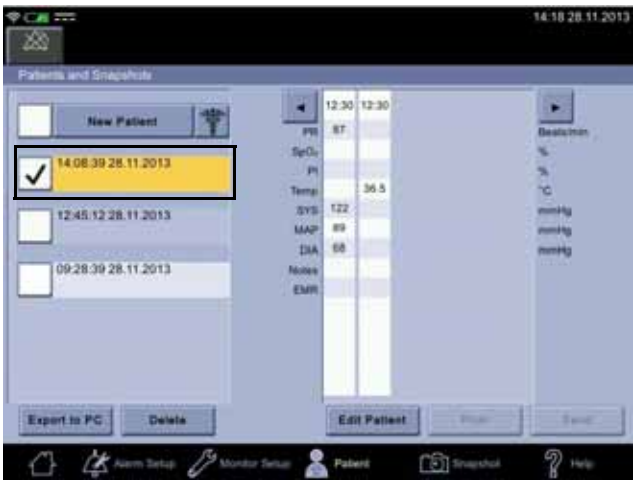
WARNING
Make sure the selection(s) is/are correct before deleting. The action will take place immediately after selecting the drop-down list item. There is no way to restore entries that have been erroneously deleted.

6. Select ***Close*** to return to the ***Patient and Snapshots*** screen.

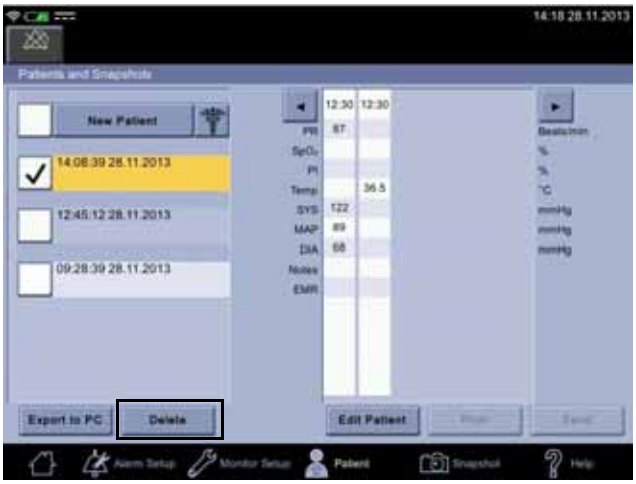
Deleting patient history

Deleting patient history is possible only if there no pending transmissions to the EMR. If there is an absolute need to delete local history, contact service.

1. Select the ***Patient*** screen.
2. Select a patient in the patient history list.



3. Select ***Delete***.



4. Confirm the deletion with ***Confirm*** or cancel the deletion with ***Cancel***.

WARNING
Make sure the selection is correct before selecting ***Confirm***. The action will take place immediately after confirmation. There is no way to restore patient entries that have been erroneously deleted.

Troubleshooting

The printer does not print

The printer may be unavailable if:

- The user has exited the ***Patient*** screen before the print command was sent to the printer.
- The battery is nearly depleted. No printouts of any type will print.
- The monitor is too hot.
- The paper is out.
- The printer option was not ordered.

Transmission to the EMR is unavailable

If the problem persists, contact service to set up wireless and/or EMR connection.

Patient search is unavailable

Contact service to set up wireless and/or EMR connection.

Forgotten password or ID

Contact hospital IT to reset the password or provide the ID.

Barcode reader does not work

Unplug and reconnect the barcode scanner. If the problem persists, contact service.

Red light in barcode reader

There is not sufficient power for barcode reader. Contact service.

6 NIBP

Description

The NIBP parameter in the monitor is available with two types of NIBP technologies: one calibrated to intra-arterial pressure (DINAMAP™ SuperSTAT) and one calibrated to the auscultatory method.

The type of NIBP technology used by the monitor is indicated in the ***Monitor Setup > NIBP*** screen. Refer to "NIBP settings" on page 6-12.

Refer to "Principles of noninvasive blood pressure determination (NIBP)" on page C-1 for a description of the principles of operation of NIBP. User interface options, instructions for use, and alarms are the same for all technologies. The NIBP parameter is included in all models. Blood pressure is measured noninvasively in the monitor by oscillometric method.

NOTE

For neonatal populations, the reference is always the intra-arterial pressure monitoring method. The monitor automatically switches from Auscultatory to SuperSTAT whenever a neonatal cuff is detected.

The monitor has four NIBP modes: ***1.*** Single determination, ***2.*** STAT, ***3.*** Cycle, ***4.*** Profile cycle. The mode is selected by the user. The actual NIBP determination is automated and once it is complete, the values for systolic pressure, diastolic pressure, mean arterial pressure, and pulse rate (if SpO_2 is not active) are shown in their respective windows.

Before each NIBP determination, the monitor ensures the cuff has been deflated from the previous determination. The determination is delayed until this condition is met. The monitor senses the type of hose being used and automatically uses adult/pediatric monitoring parameters or neonate monitoring parameters as appropriate.

NOTES

Audible and visible alarms occur in monitoring mode when any of the values for systolic pressure, diastolic pressure, or pulse rate (if sourced by NIBP) are outside their selected high or low limits. Alarms are disabled in spot-check mode.

If the internal battery is depleted during NIBP determination, the cuff will deflate automatically.

When the ***Battery Low*** (5 minutes left) alarm is signaled, NIBP is disabled and the monitor will automatically shut down in 5 minutes. Connect the power cable to continue using the monitor.

CAUTION

The RADIAL-CUF has been validated for use only with GE SuperSTAT algorithm for adult obese patients. The RADIAL-CUF has not been validated for use against the GE Auscultatory algorithm. Refer to the RADIAL-CUF instructions for use for sensor requirements.

Differences in intra-arterial and auscultatory references

Intra-arterial reference

The intra-arterial reference algorithm was developed based on blood pressure values obtained with an intra-arterial catheter (e.g., central aortic). The accuracy of the DINAMAP™ SuperSTAT algorithm has been demonstrated through a clinical study to meet or exceed AAMI SP10 requirements where the reference measurements were made from an intra-arterial catheter placed in the ascending aorta.

Auscultatory reference

The auscultatory reference algorithm was developed based on noninvasive blood pressure values obtained with a sphygmomanometer, a stethoscope, and listening to the Korotkoff sounds. The accuracy of the auscultatory algorithm has been shown to achieve an overall A/A grade using the BHS study protocol where reference measurements are made through auscultation with sphygmomanometers.

DANGER

Connect cuffs and inflation systems only to systems designed for noninvasive blood pressure monitoring. Devices with luers and locking luer connectors may be inadvertently connected to intravascular fluid systems that may allow air to be pumped into a blood vessel.

WARNINGS

The blood pressure measurement may not be accurate with patients who are experiencing seizures or tremors.

Carefully route the external AC/DC power converter, air hoses, and all cables to reduce the possibility of entanglement or strangulation.

Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure and the monitor may not be able to complete a measurement on patients of this type because of the safety time limit (maximum allowed time for the parameter: 120 seconds for adult/pediatric and 85 seconds for neonatal).

In spot-check mode, the monitor displays the results of the last blood pressure determination. The measurement data is automatically stored in patient data. If the monitor remains in spot-check mode and a patient's condition changes between one determination and the next, the monitor will not detect the change or indicate an alarm condition.

It is possible to set the alarm limits for pulse rate outside of the operating range for the NIBP parameter. Under such conditions, an alarm will not occur.

CAUTIONS

Do not use an infant cuff with an auscultatory reference. The neonatal #5 cuff and neonatal hose may be used on patients with an arm circumference of 8 - 15 cm.

Blood pressure cuffs should be removed from the patient when the monitor is not in use. If the extremity remains cuffed under these conditions or if the interval between blood pressure determinations is prolonged, the patient's limb should be observed frequently and the cuff placement site should be rotated as needed.

The pulse rate derived from an NIBP determination may differ from the heart rate derived from an ECG waveform because the measurement derived from NIBP measures peripheral pulses, not electrical signals or contractions from the heart. Differences may occur because electrical signals at the heart occasionally fail to produce a peripheral pulse or the patient may have poor peripheral perfusion. Also, if a patient's beat-to-beat pulse amplitude varies significantly (e.g., because of pulsus alternans, atrial fibrillation, or the use of a rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic, and an alternate measurement method should be used for confirmation.

Several conditions may cause the NIBP parameter to calculate and display only the mean arterial pressure without systolic and diastolic readings. These conditions include very low systolic and amplitude fluctuations, so an accurate calculation for these values can't be made (e.g., patient in shock); too small of a difference between systolic and MAP calculations in relationship to the difference between diastolic and MAP; or a leak has occurred in the cuff or connector outside the monitor.

Avoid contact with the cuff while monitoring, since it may cause inaccurate blood pressure values.

Devices that exert pressure on tissue have been associated with purpura, skin avulsion, compartment syndrome, ischemia, neuropathy and/or thrombosis. To minimize these potential problems, especially when monitoring at frequent intervals or over extended periods of time, make sure the cuff is applied appropriately and examine the cuff site and the limb distal to the cuff regularly for signs of impeded blood flow.

NOTES

The monitor is designed for use only with GE BP dual-tube cuffs.

Use only GE blood pressure cuffs. The size, shape, and bladder characteristics can affect the performance of the instrument. Inaccurate readings may occur unless GE blood pressure cuffs are used.

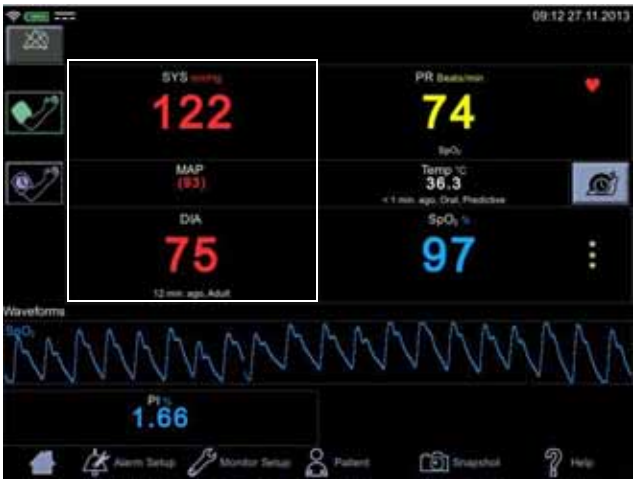
A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease heart rate.

Oscillometric method

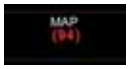
The oscillometric method of determining NIBP is accomplished by a transducer that measures small variations in cuff pressure resulting from the pulsatile flow of blood in the patient's artery while the air pressure in the cuff is varied. These signals are analyzed by the algorithm resulting in systolic, MAP, and diastolic pressure estimates calculated to correspond to either an intra-arterial or auscultatory reference.

NIBP on the monitor screen

The NIBP parameter field is located on the left side of the monitor screen. Blood pressure-related titles and pulse rate are displayed in red by default. The color of the unit of measurement and measurement data can be changed in configuration mode. The NIBP parameter field view varies depending on which NIBP mode is used and which part of the body is selected for the measurement.



Screen item	Description
	The start icon starts the NIBP determination process by first inflating the cuff to the target pressure. Selecting the terminating icon/red inflate icon terminates the inflation and the NIBP process altogether. The NIBP mode icon above the start icon indicates the chosen NIBP measurement mode. If a measurement is in progress and the cuff fills with air, the current pressure is displayed in digits above the start icon.

Screen item	Description
SYS 	The *SYS* value displays the label *SYS **mmHg***, which stands for: • *SYS* = systolic blood pressure. • *mmHg* = unit of measurement. Service can change the unit of measurement to kPa if desired. Limits for *SYS* can be configured in the *Alarm Setup* to trigger an alarm if the *SYS* value does not remain within limits.
MAP 	The *MAP* (mean arterial pressure) value is displayed between the *SYS* and *DIA* values. When an NIBP determination results in *MAP* only values, the *SYS* and *DIA* fields show dashes instead of numeric values. The factory default setting for *MAP* value limits is *OFF*. If enabled, limits can be configured in *Alarm Setup* to trigger an alarm if the *MAP* value does not remain within user set limits.
DIA 	*DIA* stands for diastolic blood pressure. Limits for *DIA* can be configured in *Alarm Setup* to trigger an alarm if the *DIA* value does not remain within limits. The line below the diastolic value displays the text *1 min ago, Adult, Left*, which stands for: • *1 min ago* = Time lapsed from the last measurement. • *Adult* = Cuff type recognized by the monitor. If the cuff is changed, the monitor will recognize the new cuff during the initial inflation period of the next NIBP determination. If the monitor detects a neonatal cuff, the default target pressure for neonates is used. • *Upper left arm* = Cuff position during the last measurement. Cuff position can be changed in the *Monitor Setup > NIBP* screen.
Auto Mode 	If a *STAT*, *Cycle* or *Profile* NIBP measurement cycle has been selected, countdown numbers below the NIBP mode icon indicate time left before the next NIBP measurement. NOTE The auto mode option can be selected also in the *Monitor Setup > NIBP* tab.

Screen item	Description
PR 	***PR*** is the SpO_2 derived pulse rate. If SpO_2 is not being measured or available, ***PR*** is the NIBP derived pulse rate. The pulse rate label consists of the name and the unit of measure used. A heart symbol is displayed next to ***PR***. This symbol blinks and an audio sound is signaled if SpO_2 is active and a pulse is detected. Limits for ***PR*** can be configured in ***Alarm Setup*** to trigger an alarm if the ***PR*** value does not remain within limits.

Alarms associated with NIBP

Physiological and technical alarms are categorized by priority level:

When an NIBP measurement invokes an alarm:

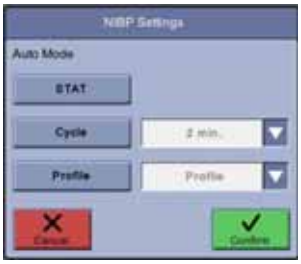
- The monitor will sound an audible alarm signal.
- An LED light will illuminate at the top of the monitor.
- A message will be displayed in the alarm area of the monitor screen.
- The NIBP value exceeding its limit will be highlighted on screen.

NOTE

Technical error conditions related to NIBP are first displayed under the DIA value and after 10 seconds as a low priority alarm.

To respond quickly to an alarm, select the silence icon in upper left corner of the screen. Once this icon is selected, the audible alarm will remain silent for two minutes. The alarm will reactivate if the monitor continues to receive NIBP measurement information. To acknowledge an alarm, select the alarm message on the notification area.

NIBP modes of operation



The monitor has several NIBP modes that can be selected by the user. NIBP determinations are automated and, upon completion, the values for systolic pressure, diastolic pressure, mean arterial pressure, and pulse rate (if SpO_2 is not active) are shown in their respective windows. NIBP can be measured once or have as many measurements as possible within a given time frame using ***STAT***, ***Cycle*** or ***Profile***. NIBP auto mode can be selected in ***Monitor Setup > NIBP*** or selecting the auto mode icon on the screen and then making the selection.

Profile mode can be configured in password-protected ***Default Setup***. The ***Profile*** settings allow the user control over the sequence of these determinations. The user may establish multiple groups of NIBP determination cycle sequences, each with a defined number of NIBP intervals with a defined duration. When that sequence expires, the next sequence takes over until all sequences have completed. As an example; one ***Profile*** could comprise of 4 determinations at 5-minute intervals followed by 8 determinations at 60-minute intervals, resulting in a total of 12 determinations over a period of 8 hours and 15 minutes.

NOTES

If an alarm condition emerges and the silence icon is selected, the current determination will be completed, but subsequent repeated determinations will not be carried out.

When an automated ***STAT***, ***Cycle*** or ***Profile*** measurement is being performed, the auto mode button in the ***Monitor Setup > NIBP*** is disabled.

Adaptive target inflation pressure

If several NIBP determinations are performed on the same patient, the monitor will adjust the target inflation pressure based on previous determination results for that patient. Adaptive target inflation pressure is always patient-specific. When the patient is discharged, results of his/her NIBP determinations will not be used for the next patient. Adaptive history is cleared if a single NIBP measurement is not performed for more than two minutes. Adaptive history is not cleared in ***STAT***, ***Cycle*** or ***Profile*** modes.

Single NIBP determinations

A normal, uninterrupted manual determination takes about 40 seconds but varies from patient to patient and is affected by the size and tightness of the cuff. Following a determination, the cuff pressure must drop below 5 mmHg (neonate) or 15 mmHg (adult) before another determination can be started.

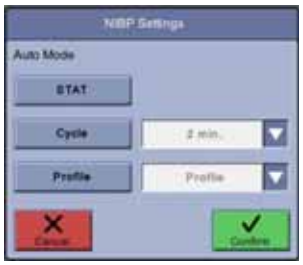
Single NIBP determinations are initiated by selecting the inflate icon. If you want to terminate a single NIBP determination, select the red stop NIBP icon. Upon completion of an NIBP determination, the values are displayed in the ***Systolic***, ***Diastolic***, ***MAP***, and ***Pulse Rate*** (if SpO_2 is not active) windows. The values remain on the display until they are older than the user-configured timeout for display of NIBP values (this can be set in ***Monitor Setup > Advanced > Default Setup***). A single measurement can be taken between automatic measurement intervals in ***Cycle*** and ***Profile*** modes periodic measurements. The venous return time affects when next measurement can be initiated. Refer to "Venous return for cycle and profile" on page 6-11 for information on venous return time.

STAT NIBP determinations

STAT mode allows you to take as many determinations as possible within a 5-minute time period, venous return included. The monitor will begin another determination once the pressure is below 5 mmHg for 8 seconds (neonatal) or 15 mmHg for 4 seconds (adult/pediatric), unless the 5-minute period has ended or STAT mode has been canceled. After the first STAT determination, subsequent determinations display an early systolic value in the Systolic window. STAT mode only: Early systolic values are displayed as dimmed numeric values.

1. Select the auto mode icon on the home screen.
2. Select ***STAT***.
3. Select ***Confirm*** to confirm the selection or select ***Cancel*** to cancel selection.

4. Select the green ***STAT*** auto mode icon on the left side of the screen to start a 5-minute period of STAT determinations. If it becomes necessary to stop the determination at any point, select the red ***STAT*** auto mode icon.



NOTES

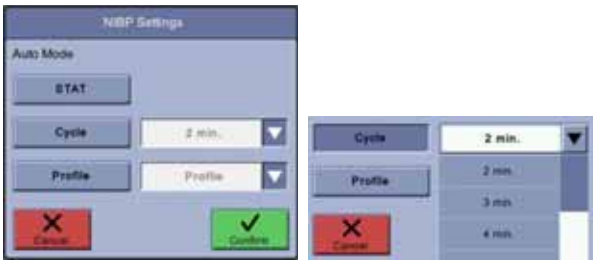
Clinical alarms for NIBP and NIBP-derived pulse rate are disabled during STAT measurement. These are enabled after the STAT measurement is complete.

If STAT mode is started when a determination is already in progress, that determination becomes the first in the series of STAT determinations.

Auto cycle determinations

Auto cycle mode automatically starts determinations at user-defined intervals. In the auto cycle mode, the pressure must be below 5 mmHg (neonate) or 15 mmHg (adult) for at least 30 seconds before the next auto determination will be started.

1. Select the auto mode icon on home screen.
2. Select ***Cycle*** in the drop-down list.



3. Select the cycle length (measurement at every 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 20 min, 30 min, 60 min, 90 min and 120 min).

NOTE

Single determinations can be taken while in auto or profile cycle mode without affecting the starting time for the next auto or profile determination. However, venous return time will be honored before the next auto or profile determination starts. If a single measurement lasts longer than when the next auto cycle is supposed to start, the next auto cycle measurement is skipped. You can also change the time interval while in auto cycle mode.

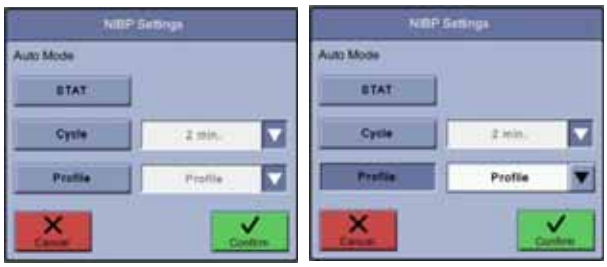
4. Select ***Confirm*** to confirm the selection or select ***Cancel*** to cancel selection.

5. Select the green ***Cycle*** auto mode icon on the left side of the screen to start the cycle. When a determination is complete, the time till the next determination appears above the auto mode icon. If it becomes necessary to stop the determination at any point, select the red ***Cycle*** auto mode icon.

Profile cycle determinations

A profile cycle is a pre-defined set of intervals for a series of NIBP measurements. The number of determinations and time for an interval can be adjusted in configuration mode. Five available profiles can be renamed in configuration mode to make these descriptive. If a profile does not have any number of determinations and time intervals, its name is not displayed. If no profiles are defined, the ***Profile*** icon is not available.

1. Select the auto mode icon on the home screen.
2. Select ***Profile***.



3. Select a profile in the drop-down list. The names may differ from sample profiles in the image above.
4. When you have selected a profile name, select ***Confirm***.

5. Select the ***Profile*** auto mode icon on the left side of the screen to start the cycle. When a determination is complete, the time till the next determination appears above the auto mode icon. If it becomes necessary to stop the determination at any point, select the red ***Profile*** auto mode icon.

Venous return for cycle and profile

If a cycle or profile measurement is still in process when the next cycle measurement should take place, the next cycle measurement will be skipped. In case the next cycle measurement should take place right after the current measurement, the monitor will delay the measurement for venous return. If there is too much pressure or another problem, a lime green cuff image is displayed. Selecting this icon will acknowledge the error condition and return the green inflate icon on screen.

NIBP alarm limits

The NIBP alarm limits are displayed as stated below:

- When a new patient is admitted, dashes are displayed instead of NIBP alarm limits.
- When a cuff is detected, corresponding NIBP alarm limits (adult or neonatal) are displayed.

NOTE

The NIBP alarm limit shortcut on the home screen becomes available when the monitor detects either neonate or adult/pediatric hose and a first NIBP determination has been completed.

- When a determination is complete, the NIBP alarm limits for the detected cuff are displayed for a predefined expiration time (set in configuration mode).
- When latching is selected for an NIBP alarm, the NIBP alarm limits will not expire.
- Alarm limits remain on screen while the patient is admitted.
- Numeric key pad shortcut for alarm limits is disabled when the limits are not displayed.

NIBP settings

You should always check the NIBP technology configuration setting before using the monitor. Monitors located in the same clinical area may have different NIBP technology configuration settings that could result in operational differences and a delay in performing vital signs measurements. Refer to "NIBP setup" on page 3-21 for items to check.

Taking NIBP measurements

During the whole NIBP procedure, the operator should remain in a position where the patient and the monitor are within easy reach.

Procedure

1. For improved measurement accuracy, have patient in a comfortable position with legs uncrossed and back and arms supported. The middle of the cuff should be at the level of the heart during the measurement. The patient should relax for 5 minutes before the first measurement is performed. The patient should not talk during the procedure.

NOTE

If the patient is pregnant or is pre-eclamptic, consult with the doctor about whether NIBP can be performed.

2. Connect the end of the air hose with quick-release clips to the NIBP connector on the left side of the monitor. Make sure that the hose is not kinked or compressed.

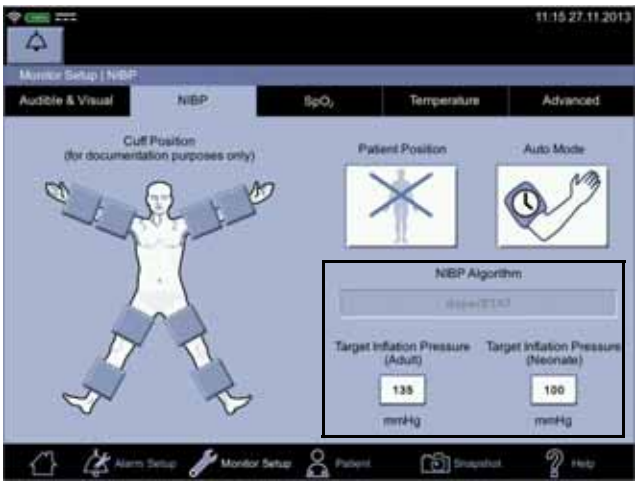
NOTE

To disconnect the hose from the monitor, squeeze the quick-release clips together and pull the plug from the NIBP connector.

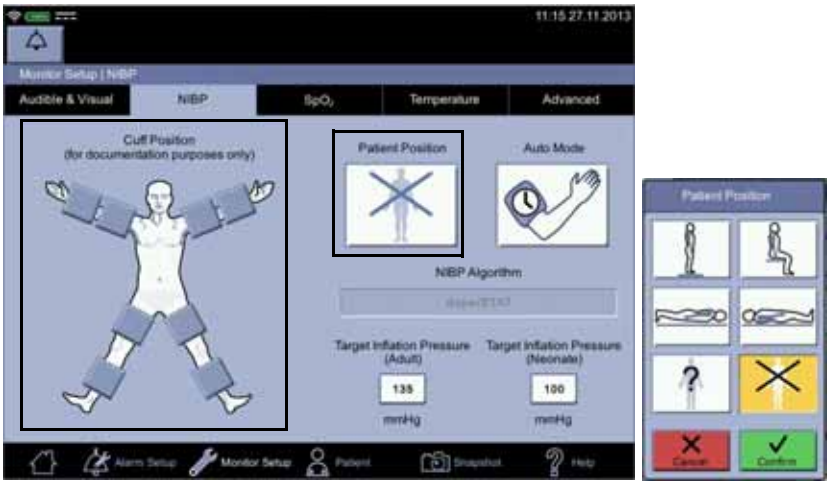
3. Set patient-specific ***Upper*** and ***Lower*** limits (possible only in monitoring mode). Refer to "Alarm limit setup" on page 3-14 for instructions and to "Physiological alarm conditions" on page 4-8 for limit ranges.

NOTE

If you are performing a measurement with a neonatal or pediatric cuff, adjust the limits.



4. Choose the appropriate blood pressure measurement site and patient position.



5. For the upper arm, measure the circumference of the upper arm midway between the elbow and shoulder to determine what size of upper arm cuff should be used. Proper cuff sizing is crucial for an accurate BP measurement. When cuff sizes overlap for a specified cuff, it is recommended to use the larger size cuff. Familiarize yourself with the operator warnings.

   DANGER

   Selecting a correct hose and cuff is *very* important. ***Do not mix neonatal and adult hoses! An adult hose pressure is extremely dangerous for neonates.*** The air hoses are color-coded according to patient population. The gray 12- or 24-foot hose (3.66 m or 7.3 m) is required on patients who require cuff sizes from infant through thigh cuffs. The light blue 12-foot hose (3.66 m) is required for the neonatal cuff sizes #1 through #5.

   Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and to select the proper size cuff. If it becomes necessary to move the cuff to another limb, make sure the appropriate size cuff is used.

   NOTE

   Use only GE BP cuffs. The size, shape, and bladder characteristics can affect the performance of the instrument. Inaccurate readings may occur unless GE BP cuffs are used.

6. Check the cuff, tubing, adapters, and hose for any signs of damage or wear. Replace if any signs of damage. Do not inflate cuff when unwrapped. If accessories are not clean, obtain clean accessories for this measurement or refer to "Cleaning" on page B-4.

   CAUTION

   Do not use the cuff if structural integrity is suspect.

7. Connect the cuff to the air hose. Make sure the connections are secure. Refer to the instructions on GE BP cuffs and hoses.

   CAUTION

   Never connect cuffs or hoses made by other manufacturers to GE BP accessories.

8. Inspect the limb for skin integrity.

   WARNINGS

   Do not apply cuff to areas where skin is not intact or tissue is injured, or where dermal disruption is at greater risk. Ensure the rough side of the closure does not contact the skin; it may cause irritation.

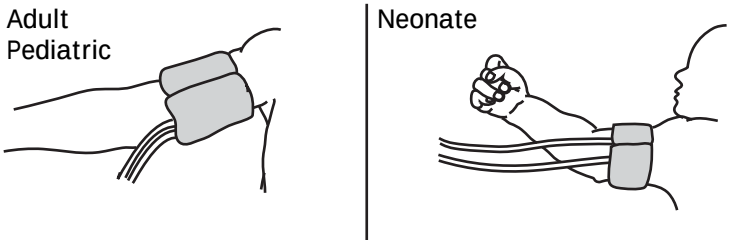
   Do not apply cuff to limb used for intravenous infusion, oximetry measurement, arterial monitoring, where AV fistulas are present, or areas where circulation is compromised. Assess limb for risk of lymphedema (due to mastectomy, etc). It is always good clinical practice to document the site of the limb where the BP is taken.

9. Palpate artery and align the artery mark on the cuff over the patient's brachial or appropriate artery.
10. Squeeze all air from the cuff and confirm that the connection is secure and unoccluded and that tubing is not kinked.

    NOTE

    Avoid compressing or constricting the NIBP pressure tubes.

11. For the upper arm, wrap the cuff around the bicep ensuring the index line falls between the range marks on the cuff.



12. Ensure the cuff is snug enough to allow only two fingers to be inserted between the cuff and patient's arm. Ensure that hook and loop closures are properly engaged so that pressure is evenly distributed throughout cuff. Cuff should not be so tight as to prevent venous return between determinations. Always refer to the instructions for use for complete information on the proper use of your BP cuff.

    CAUTION

    Using a cuff that is too tight will cause venous congestion and discoloration of the limb, but using a cuff that is too loose may result in no readings and/or inaccurate readings.

13. Select the ***Patient Position*** and ***Target Inflation Pressure*** (if necessary) in the ***Monitor Setup > NIBP*** screen.

NOTES

If the patient is standing, sitting, or inclined, ensure that the cuffed limb is supported to maintain cuff at level of patient's heart. If the cuff is not at heart level, the difference in systolic and diastolic values due to hydrostatic effect must be considered. To correct for the hydrostatic effect on values not measured not at the heart level, add 1.90 mmHg to the values for every 2.54 cm (one inch) above heart level or subtract 1.90 mmHg from the values for every 2.54 cm (one inch) below heart level.

The initial target pressure may need to be adjusted if the patient bruises easily, is elderly, or for another reason. As there are ***Target Inflation Pressure*** limits for adults and neonates, make sure you adjust the correct limit.

Choosing the position of the cuff is for documentation purposes only. Please refer to the cuff's instructions for use for further information.

14. Select the home icon.

15. If you want to perform a single determination, select the inflate icon to inflate the cuff and start the measurement process.

16. If you want to perform an automated determination, select the auto mode icon.

17. Select ***Cuff position*** and ***Auto Mode*** in the ***NIBP Settings*** screen. The mode must be selected for each measurement. The selected mode is displayed on the auto mode icon.
18. Select ***Confirm*** to confirm the changes and to start the determination or select ***Cancel*** to cancel the changes.

NOTES

If you want to terminate any NIBP measurement when the cuff is inflating, select the red inflate icon.

If the green inflation waiting icon is selected between cycle or profile measurements, the monitor will initiate an NIBP determination. This does not change the previous cycle or profile schedule of NIBP determinations.

When the measurement is complete, the monitor will sound two beeps, automatically create a snapshot, and display measurement values on screen for a period defined in configuration mode. Service personnel can change the display time upon request.

19. To review patient data, enter the ***Patient*** screen and select ***Measurements*** to launch a screen with historical patient-related data. The newest measurement data is posted on the left side of the matrix.
20. Clean and disinfect the NIBP cuffs as instructed in "Cleaning and disinfecting blood pressure cuffs and air hoses" on page B-6".

Taking NIBP measurements on different patients

When an NIBP determination is initiated on a new patient, the previous patient must be discharged first. The monitor will then clear previous NIBP values and use a default target inflation pressure for this new patient. If several NIBP determinations are taken, the monitor starts to adjust the target inflation pressure.

When NIBP measurements are performed: 1) the monitor will use a previous NIBP value for adaptive target inflation pressure as long as this is displayed on the screen. 2) the NIBP values are displayed for a maximum of 30 minutes or until another determination is initiated. When the values on the screen expire or the patient is discharged, the adaptive target pressure will be automatically cleared. If a patient's condition changes between one determination and the next, the monitor will not detect the change or indicate an alarm condition until the next NIBP determination values are published on the display.

In auto mode, the previous NIBP systolic pressure is used for adaptive target inflation pressure independent of the length of time the values are displayed.

NOTES

The adaptive target inflation pressure is cleared when 1) the patient is discharged or 2) the values on screen expire.

The value will not be cleared if an auto mode measurement is active.

Alarms

Upon completion of a determination (the monitor has to be in monitoring mode) that results in systolic, diastolic and MAP values, these values are checked against the appropriate set of patient type limits based upon the hose type detected. The final STAT result is checked against alarm limits. When the limit alarms are active, they can be silenced by selecting the silence icon or acknowledging an alarm message.

If an auto cycle or profile cycle determination results in a limit alarm, a message is displayed on screen and a single repeat determination is taken to verify the alarm. If an auto cycle or profile cycle measurement results in other failure than NIBP Not Available or NIBP Overpressure, the monitor attempts to perform maximum of ten consecutive measurements to achieve a proper measurement.

NIBP specifications

Cuff pressure range (Normal operating range)	0 to 290 mmHg (adult/ped) 0 to 145 mmHg (neonate)
Blood pressure accuracy (Auscultatory)	Complies with ANSI/AAMI Standard SP-10:2002 (mean error ≤ 5 mmHg, standard deviation ≤ 8 mmHg).
Blood pressure accuracy (SuperSTAT)	Complies with ANSI/AAMI Standard SP-10:2002 (mean error ≤ 5 mmHg, standard deviation ≤ 8 mmHg).
Maximum determination time	120 s (adult/ped) 85 s (neonate)
Overpressure cutoff	300 to 330 mmHg (adult/ped) 150 to 165 mmHg (neonate)
BP range (Auscultatory)	
Systolic	30 to 245 mmHg (adult/ped)
MAP	15 to 215 mmHg (adult/ped)
Diastolic	10 to 195 mmHg (adult/ped)

BP range (SuperSTAT)	
Systolic	30 to 290 mmHg (adult/ped) 30 to 140 mmHg (neonate)
MAP	20 to 260 mmHg (adult/ped) 20 to 125 mmHg (neonate)
Diastolic	10 to 220 mmHg (adult/ped) 10 to 110 mmHg (neonate)
Pulse rate range (Auscultatory)	30 to 200 beats/min (adult/ped)
Pulse rate range (SuperSTAT)	30 to 240 beats/min (adult/ped) 30 to 240 beats/min (neonate)
Pulse rate accuracy	± 3.5% or 3 bpm, whichever is higher
NOTES NIBP performance and accuracy have only been confirmed using GE hoses and cuffs. The SuperSTAT algorithm is used for all neonate NIBP determinations.	

NIBP troubleshooting

Overpressure

If an overpressure condition occurs, the word ***Overpressure*** appears below the diastolic value and the pressure is released. Then a blue error message appears in the notification area.

1. Select the message to acknowledge it. The icon will turn a green inflate icon.

A STAT or Cycle measurement will not continue before this measurement is terminated.

2. Check for hose and tubing blockage.
3. Try to measure the NIBP again.

Increase in determination time

Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure.

Ask the patient whether there is need for medical consultation due to arrhythmias.

No determination

If an NIBP determination was unable to be completed, the following may be the cause:

- Determination failed (no complexes). Reapply cuff and restart the NIBP determination.
- Inflation timeout. Pressure leak. Check or replace hose or cuff.
- Determination cannot be made due to an excess amount of air in the cuff.
- Maximum allowed time reached for a single determination.
- Timeout at single level. Maximum allowed time reached for a single cuff pressure time.
- Total timeout. Maximum allowed time reached for a total cuff pressure time.

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7 GE TruSignal SpO_2

Description

The SpO_2 parameter in the monitor is available in three different technologies:

- GE TruSignal
- Nellcor OxiMax™
- Masimo rainbow® SET®

The SpO_2 technology logo on the left side of the monitor, above the physical connector, will disclose which technology the monitor is equipped with. If you want to use a different SpO_2 technology than your monitor is currently equipped with, contact service to discuss the procedure.

The SpO_2 function is calibrated to read functional arterial oxygen saturation. When a suitable SpO_2 sensor is connected to the monitor and to the patient, the measurement values will be shown on the screen. Pulse rate derived from SpO_2 appears in the ***PR (Pulse Rate)*** window and updates continuously. The primary source of pulse rate is always SpO_2, i.e., if SpO_2 is measuring when an NIBP determination is completed, the pulse rate derived from NIBP is not displayed. A tone sounds at a rate corresponding to the pulse rate and at a pitch corresponding to the SpO_2 saturation level. The pitch is highest at 100% oxygen saturation, and it continuously decreases as the saturation level falls.

CAUTION

The pulse rate derived from SpO_2 is a value calculated from oxygen levels. The pulse rate is not equal to the patient's actual heart rate.

Audible and visual alarms occur when SpO_2 levels are outside the alarm limits. and the monitor is in monitoring mode. When a parameter status alarm occurs, an alarm message appears at the top of the screen (rectangle in the image above).

SpO_2 safety

WARNINGS

Many factors may cause inaccurate readings and alarms, decreased perfusion, and/or low signal strength:

Interfering substances:

- Carboxyhemoglobin may erroneously increase SpO_2 readings.
- Methemoglobin (MetHb) usually represents less than 1% of the total Hgb, but in the case of methemoglobinemia that can be congenital or induced by some IV dyes, antibiotics (such as sulphas), inhaled gases, etc., this level increases sharply. Methemoglobin may cause inaccurate SpO_2 readings.
- Intravascular dyes (such as indocyanine green, methylene blue, etc.) at certain concentrations may cause inaccurate SpO_2 readings and/or decreased perfusion and corresponding signal strength, potentially causing inaccurate SpO_2 readings.
-Nail polish and artificial nails may cause inaccurate readings.

Physiological characteristics:

Some physiological characteristics may cause decreased perfusion and/or low signal strength and may potentially cause inaccurate SpO_2 readings:

- Cardiac arrest, hypotension, shock, severe vasoconstriction, severe anemia, hypothermia, venous pulsations, congestions, darkly pigmented skin, ventricular septal defects (VSDs)

Environmental conditions:

Some environmental conditions may cause interference or artifact and may potentially cause inaccurate SpO_2 readings.

- Excessive ambient light sources (e.g., infrared heat lamps, strobe lights, bilirubin lights, direct sunlight, operating room lights). To prevent such interference, cover the sensor with opaque material.
- Electrical interference/Electrosurgery
- Defibrillation - May cause inaccurate reading for a short amount of time.
- Excessive patient/sensor motion. Artifact can simulate an SpO_2 reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

Sensor placement:

- Sensor placement on the same extremity as a blood pressure cuff, arterial catheter or intravascular line; or arterial occlusion proximal to the sensor; or a sensor below the heart level may cause decreased perfusion and/or low signal strength and potentially cause inaccurate SpO_2 readings.
- Poor sensor fit may cause decreased or low signal strength and potentially cause inaccurate SpO_2 readings.
- Do not allow tape to block the sensor light emitter and detector as this may cause decreased perfusion and/or low signal strength and potentially cause inaccurate SpO_2 readings.
- Before using the GE TruSignal sensor, carefully read the GE sensor instructions for use.

WARNING

As with any wrap or clip-on sensor, pressure is exerted. Be cautious in using a wrap or clip-on sensor on patients with compromised circulation (e.g., peripheral vascular disease or vasoconstricting medications).

Allow sensor and cable to dry completely after cleaning. Moisture and dirt on the connector can affect the measurement accuracy.

Inaccurate SpO_2 data can result if a sensor is past its useful life. Therefore, re-evaluate the measurement periodically by performing additional assessment of the patient equipment, including consideration of use of alternate monitoring methods such as direct measurement of arterial oxyhemoglobin saturation (SaO_2).

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs, then check for conditions that may cause inaccurate SpO_2 readings. If the problem is still not resolved, check the SpO_2 module or sensor for proper functioning.

Oximetry performance may be impaired when patient perfusion is low (less than 0.3%) or signal attenuation is high.

A pulse oximeter or CO-oximeter should not be used as an apnea monitor.

A pulse oximeter should be considered an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition. Check that the pulse oximetry waveform is physiological in shape to ensure waveform quality and minimize noise spikes caused by motion conditions.

If you deactivate the ***SpO2 Sensor Off*** alarm, keep the patient under close surveillance.

Single-use products are not designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, and cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization and/or reuse.

Clean the surface of the probe before and after each patient use.

Do not loop the sensor cable into a tight coil or wrap around the device, as this can damage the sensor cable.

CAUTIONS

Do not sterilize reusable sensors by irradiation, steam, or ethylene oxide. See the sensor manufacturer's instructions for cleaning, sterilization, or disinfecting methods.

Do not place SpO_2 sensor on patient during magnetic resonance imaging (MRI). Adverse reactions include potential burns to patients as a result of contact with attachments heated by the MRI radio frequency pulse, potential degradation of the magnetic resonance image, and potential reduced accuracy of SpO_2 measurements. Always remove oximetry devices and attachments from the MRI environment before scanning a patient.

Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

Placing a sensor distal to an arterial line may interfere with adequate arterial pulsation and compromise the measurement of SpO_2.

The sensor disconnect error message and associated alarm indicate that the sensor is either disconnected or the wiring is faulty. The user should check the sensor connection and, if necessary, replace the sensor, interconnect cable, or both.

Placing a sensor on a polished or an artificial nail may affect accuracy.

Patient safety:

Do not place any clip-on sensor in a patient's mouth, on their nose or toes, on their thumb, or across a child's foot or hand.

Prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. Observe the sensor site frequently to assure adequate distal circulation. Sensor sites should be checked at least every 2 hours and rotated at least every 4 hours. Refer to instructions supplied with sensor.

If the sensor is not applied properly, the patient's skin could be injured or the ability of the monitor to measure oxygen saturation could be compromised. For example, a clip-on sensor should never be taped shut. Taping the sensor could damage the patient's skin or impair the venous return, thus causing venous pulsation and inaccurate measurement of oxygen saturation.

Excessive pressure from the sensor may cause necrosis of the skin.

CAUTIONS

Monitor performance:

Place the sensor so that the LEDs and the photodiode are opposite each other.

Monitor performance:

When an SpO_2 sensor is located on the same limb as the NIBP cuff, SpO_2 readings will not be valid while the cuff is inflated. If valid SpO_2 readings are required during the entire blood pressure determination, attach the SpO_2 sensor to the limb opposite the one with the blood pressure cuff.

NOTES

- A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease pulse rate.
- SpO_2 and pulse rate values are filtered by an averaging technique, which determines how quickly the reported values respond to changes in the patient's saturation. The averaging time effects time to alarm for SpO_2 saturation and pulse rate limits. For TruSignal SpO_2 technology, the averaging time is 8 seconds and cannot be changed by the user.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- Software development, software validation, and risk and hazard analysis have been performed to a registered quality system.
- GE TruSignal sensors are not made with natural rubber latex or known environmental contaminants.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter cannot distinguish between oxyhemoglobin and dyshemoglobins.
- Poor perfusion may affect the accuracy of measurement, especially when using an ear sensor.
- Check that the red light is lit in the sensor.
- Check that the waveforms (if enabled in monitor setup) and parameter values are displayed when the sensor is connected to the patient.

SpO_2 on the screen

When SpO_2 is not receiving measurement data, a double dash (--) appears in this window. When the sensor switches to operation mode, the SpO_2 parameter starts to receive data. If the data is valid, the derived SpO_2 value appears in this window and updates continuously. The values are displayed in %.

SpO_2 values are displayed on the lower right side of the monitor screen. The SpO_2 and PI values are displayed in cyan color by default. This can be changed in configuration mode. If the monitor is providing the temperature measurement the SpO_2 value will be located under the displayed temperature value.

The SpO_2 field consists of the SpO_2 label, the measured value in the middle and the measurement site underneath the parameter value. The measurement site choices are: ***Finger***, ***Nose***, ***Toe***, ***Earlobe***. The site name ***Other*** can be used to indicate it was none of the above. The default site is ***None***. Next to the measured value is a column of asterisks representing signal quality, as well as upper and lower limits for the SpO_2 value.

If the sensor is detached from the patient, the ***SpO_2*** status switches to 'off patient' and displays **--**.

NOTES

If pulse rate data from SpO_2 data is available, the ***Pulse Rate*** window is associated with this parameter and a heart symbol is displayed on screen. Refer to "Pulse rate" on page 10-1 for more information.

If accuracy for a SpO_2 derived parameter is not yet guaranteed, a dimmed value is displayed on screen.

Perfusion index measurement

The perfusion index (PI) measurement is a clinical tool that provides a dynamic numeric reflection of perfusion at the sensor site. PI is a relative value that varies from patient to patient. The perfusion index value appears in its own field under the label PI. The user can use the PI value to compare the strength of the pulse signal at different sites on a patient in order to locate the best site for the sensor, i.e., the site with the strongest pulse signal.

Signal quality values are mathematically calculated perfusion values represented by asterisks. The SpO_2 signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of a Low Signal Quality message. The more asterisks there are the better the signal quality. The better the arterial blood flow is, the better signal quality is obtained. A strong pulse signal increases the validity of SpO_2 and pulse rate data.

Changing the SpO_2 alarm limits

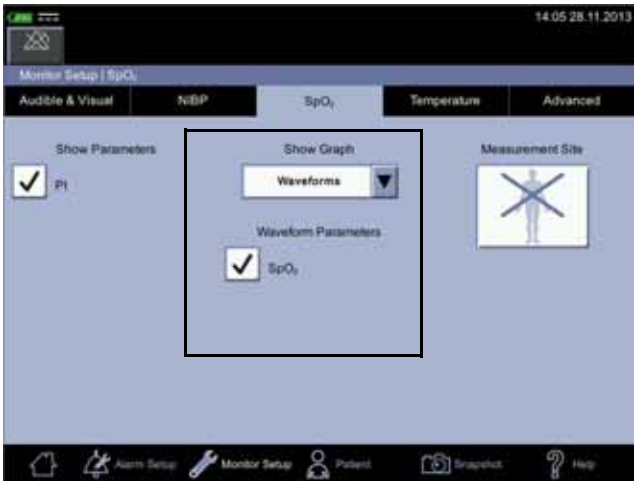
SpO_2 alarm limit adjustments can be set either A) by entering upper and lower limit values directly in a limit box on the home screen as instructed in "Using the numeric keypad" on page 3-12 or B) by adjusting limit values in the ***Alarm Setup*** screen as instructed in "Procedure for testing alarms" on page 3-11.

Pleth

The Plethysmographic waveform (Pleth) represents a real-time waveform for the relative SpO_2 pulsatile amplitude. The Pleth waveform is always automatically scaled to fit the window for the best display quality. The waveform uses the same color as the SpO_2 field.

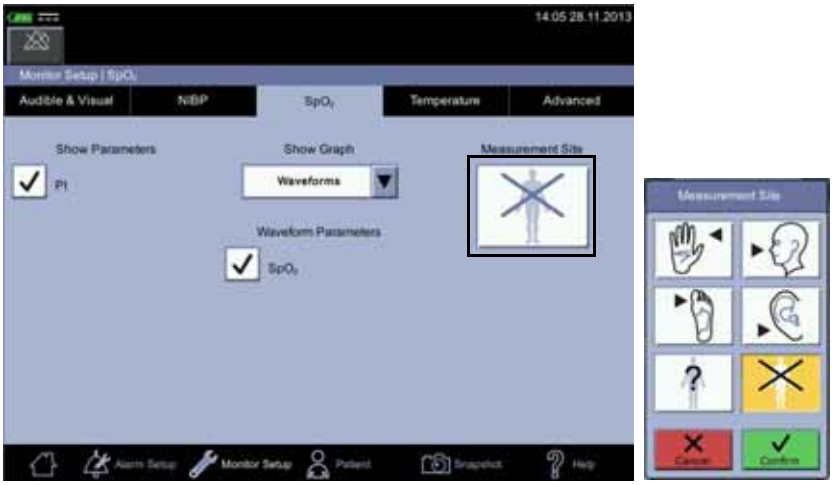
Pleth waveform settings

Select ***Waveforms*** in the drop-down menu under ***Show Graph*** in the ***Monitor Setup > SpO_2*** to display the ***Pleth***. Also select parameters to be displayed as waveforms (availability depends on which SpO_2 technology the monitor is equipped with and which options have been purchased).



SpO_2 measurement site

For documentation purposes, you can select the measurement site for SpO_2 in ***Monitor Setup > SpO$_2$*** before you start measuring SpO_2. A pop-up screen with the following images will appear: ***Finger***, ***Nose, Toe, Earlobe, Other*** or ***None***. It does not matter whether the site is on the left or right side of the patient. After the site is selected, it will be displayed on the home screen in the SpO_2 parameter window. The selection can be changed between the measurements. Admitting a new patient will reset the selection of the measurement site.



SpO_2 procedure

1. Check the label on the monitor to determine which SpO_2 technology the monitor is using. To assure optimal performance, use only accessories that are intended for that technology. If you cannot read the label, ask the nurse manager or service which SpO_2 technology is used.
2. Select a sensor that is appropriate for the patient, the clinical situation and for the SpO_2 technology used. Do not use an adult sensor on a neonatal/ pediatric patient and vice versa.

   WARNING
   Do not use a sensor, cables, or connectors that appear damaged or with exposed electrical contacts.

   Never repair a damaged sensor or cable; never use a sensor or cable repaired by others.

3. Ensure the VC150 is connected to power or the battery is fully charged.
4. Ensure the VC150 is powered on. The monitor has to display clinical mode and SpO_2 parameter on screen.
5. Connect an interface cable to the monitoring system sensor port.

6. Follow the manufacturer's guide to plug in the SpO_2 cable into the monitor and apply the proper SpO_2 sensor. The VC150 reports the appropriate sensor type in the message field when it detects the sensor.
7. *Following the directions for use supplied with the sensor*, apply the sensor to the patient.
8. Select the measurement site in ***Monitor Setup > SpO_2***, if desired. A shortcut: Select SpO_2 parameter area on the home screen to jump to the ***SpO_2*** screen.
9. Proceed with monitoring. SpO_2 measurements run continuously and can run simultaneously with other measurements.
10. Clean the sensor as instructed in "Cleaning SpO2 sensors" on page B-8".

SpO_2 sounds

The monitor provides an audible tone for each pulse detected by the SpO_2 parameter. The pitch of the audible tone is directly related to the calculated saturation value. As the saturation value increases, the pitch rises. As the saturation value decreases, the pitch frequency goes down. This audible tone is silenced while an alarm sounds or the ***Day Volume*** or ***Night Volume*** is set to ***0***. Refer to "Audible & Visual" on page 3-19 in this section.

Alarms

If the SpO_2 parameter determines the signal to be valid, SpO_2 values are displayed. In case the signal quality deteriorates to a questionable level, the ***SpO_2*** or ***Pulse Rate*** values disappear from the screen and an alarm message for lost pulse signal is generated.

Alarm timer

The user can select between monitoring mode and spot-check mode. In spot-check mode, clinical alarms and related functions are not available. If an SpO_2 measurement continues for 5 minutes uninterrupted, the monitor automatically moves from spot-check mode to monitoring mode. The alarms will be enabled in monitoring mode.

If the probe is taken off and you want to measure the same patient without alarms, select spot-check mode again.

NOTE

To prevent misuse of the device, duration of the SpO_2 spot-check mode is limited to 5 minutes.

If SpO_2 is unable to be measured for some reason, then a technical status message that indicates the reason for not measuring will appear below the parameter value. If an abnormal technical status remains for ten seconds, then a low priority alarm is created.

An abnormal technical status will create an alarm in both spot-check and monitoring mode.

TruSignal compatible accessories

All approved and VC150 compliant accessories are listed in the VC150 supplies and accessories document. Use only accessories listed in that document. If you already have an accessory that you want to use with the VC150 monitor, check whether it is listed in that document. If it not listed, do not use it with the VC150 monitor.

GE TruSignal enhanced SpO_2

GE TruSignal uses a clinically developed algorithm to perform during weak or motion-induced signals for reliable saturation readings.

WARNING

GE TruSignal technology-labeled monitors are compatible only with the GE TruSignal interconnect cables, sensors and accessories, which are available from your Innokas Medical representative. Other sensors may cause improper SpO_2 performance. Use of another pulse oximetry cable will have an adverse effect on performance. Do not attach any cable that is intended for computer use to the sensor port.

NEONATAL - The display of inaccurate pulse oximetry (SpO_2) values has been linked to the presence of poor signal strength or artifact due to patient motion during signal analysis. This condition is most likely to be encountered when the monitor is used on neonates or infants. These same conditions in adults do not impact the SpO_2 values to the same extent. We recommend the application of the following criterion when using the pulse oximetry function on neonates and infants: The SpO_2 signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of a Low Signal Quality message. Procedures or devices previously applied in your facility for SpO_2 monitoring should be used in the event the SpO_2 value from the monitor cannot be validated by the above criterion.

The pulse oximeter cannot distinguish between oxyhemoglobin and dyshemoglobins.

TruSignal SpO_2 measurement characteristics

The TruSignal pulse oximetry measurement uses a two-wavelength pulsatile system - red and infrared light - to distinguish between oxyhemoglobin (O_2Hb) and reduced hemoglobin (HHb).

The light is emitted from the oximeter sensor, which contains the light source and a photodetector.

The light source consists of red and infrared light-emitting diodes (LEDs).

The photodetector is an electronic device that produces an electrical current proportional to incident light intensity.

The two light wavelengths generated by the LEDs are transmitted through the tissue at the sensor site and are modulated by arterial blood pulsation. Since other fluids and tissues present generally do not pulsate, they do not modulate the light. The pulsatile portion of the incoming signal is used to detect and isolate the attenuation of light energy due to arterial blood flow.

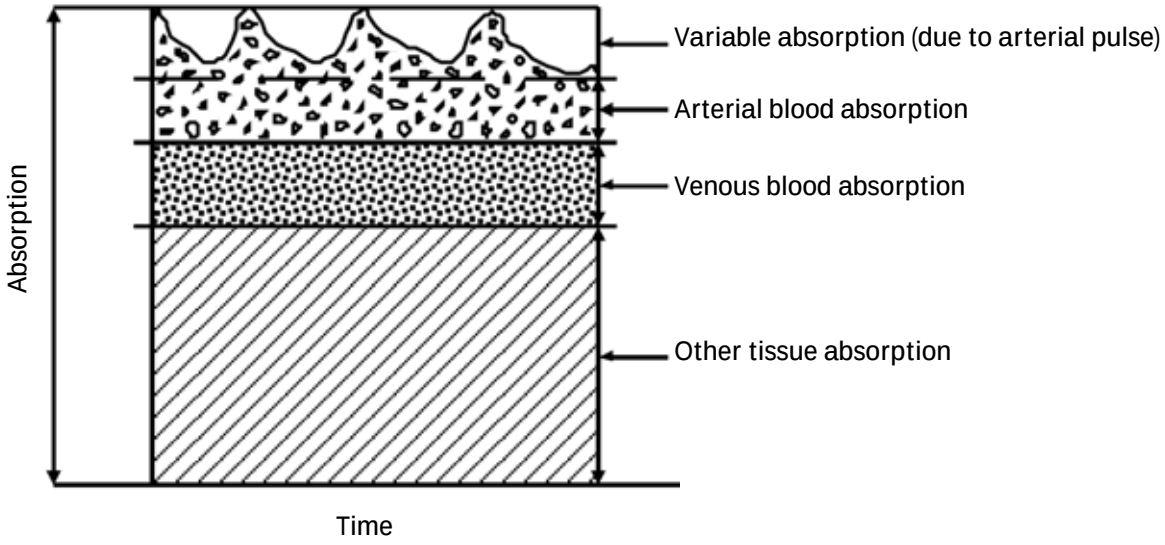


Figure 7-1. Comparative light absorption

The photodetector in the sensor converts the light intensity information into an electronic signal. Since O_2Hb and HHb absorb different amounts of the light that is emitted from the oximeter sensor, different amounts of light reach the photodetector at the selected wavelengths. The electronic signal varies according to which light source is “on” (red or infrared) and the oxygenation of the arterial hemoglobin. This information is used to calculate the relative percentage of O_2Hb and HHb.

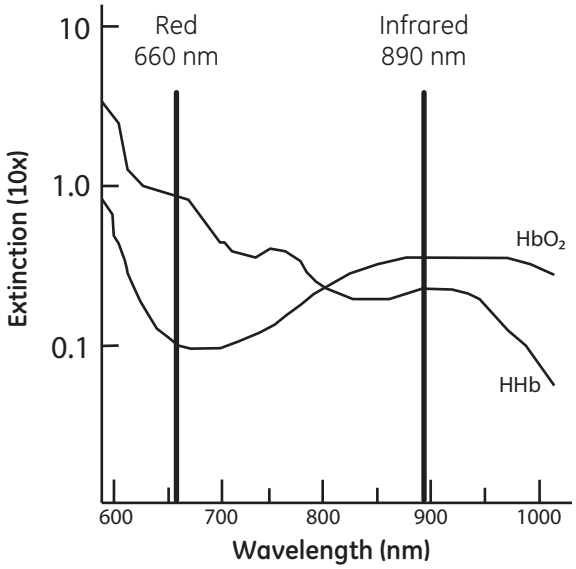


Figure 7-2. Extinction versus wavelength graph

Interfering substances

Increased patient carboxyhemoglobin may falsely increase SpO_2 readings in all brands of pulse oximeters. Therefore, saturation readings may be higher for smokers, victims of smoke inhalation, and patients with carbon monoxide (CO) intoxication. The level of increase is approximately equal to the amount of carboxyhemoglobin present.

Methemoglobin from certain therapies, dyes that change arterial pigmentation, and substances at the sensor site that contain dyes (fingernail polish, for example) may also cause erroneous readings.

Calibration

TruSignal technology uses the functional calibration method. Functional saturation is represented mathematically as the percentage of hemoglobin capable of carrying oxygen that is carrying oxygen.

$$\text{Functional } SpO_2 = \left(\frac{O2Hb}{Hb_{TOTAL} - COHb - MetHb}\right) \times 100 = \left(\frac{O2Hb}{O2Hb + HHb}\right) \times 100$$

The calculation of SpO_2 assumes 1.6% carboxyhemoglobin (COHb), 0.4% methemoglobin (MetHb), and no interfering dyes. Appreciable variation from these values will influence SpO2 accuracy.

NOTE

A hospital-grade CO-oximeter, which requires a sample of arterial blood and typically uses four or more wavelengths of light, calculates carboxyhemoglobin (COHb) and methemoglobin (MetHb) as well as O_2Hb and HHb. CO-oximeter readings and pulse oximeter readings will differ when COHb or MetHb is present.

GE TruSignal SpO_2 configuration

Refer to "SpO_2 setup" on page 3-23 to view or change the settings for Waveform and Site.

Recommended actions

- Consult the sensor instructions for use for proper sensor application.
- Inspect extension cables and sensors periodically for damage and discontinue the use of these if damage is found.
- Implement a periodic testing strategy.
- Review safety labeling based on the intended use of the equipment.

GE TruSignal SpO_2 default settings

GE Trusignal SpO_2 - Default Setup > Alarm Defaults	
SpO_2	Upper limit: OFF Lower limit: 90% Priority: Medium Latching/Non-latching: Latching
PI	Upper limit: OFF Lower limit: OFF Priority: OFF Latching/Non-latching: Non-latching

GE TruSignal SpO_2 specifications

Measurement range	
SpO_2	0 to 100%
Pulse rate	30 to 300 bpm
Perfusion Index Value (PI)	0.1 to 32.0%
Data update	
Data update period	<2 s

Accuracy Accuracy, Arms (root mean square of paired values; previously represented by ± 1 SD)	
Saturation Accuracy	
Adult*	70 to 100% ±2 digits
Neonate*	70 to 100% ±3 digits (without motion)
Adult/Neonate**	70 to 100% ±3 digits (during motion)
Low perfusion	70 to 100% ±2 digits
Pulse Rate Accuracy	
Adult /Neonate	30 to 250 bpm ± 2 bpm (rms, without motion) 30 to 250 bpm ± 5 bpm (rms, during motion)
Low perfusion	30 to 250 bpm ± 3 bpm (rms)

*Test methods used to establish SpO_2 accuracy: GE Trusignal Technology with OxyTip+/GE TruSignal sensors have been validated for no motion and motion accuracy in controlled hypoxia studies with healthy non-smoking adult volunteers over the specified SpO_2 range. SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by CO-oximetry. Subjects comprised both adult men and women and spanned a range of skin pigmentation. GE TruSignal technology with OxyTip+/GE TruSignal sensors have been validated for low perfusion SpO_2 accuracy over the specified range in a bench top testing against BioTek Index 2 patient simulator with 0.3% signal amplitude.

**GE TruSignal Technology with GE OXY-AF (equivalent to TS-AF) and GE OXY-SE (equivalent to TS-SE) sensors have been clinically validated for neonatal accuracy. Test subjects included 28 neonates and 1 infant (15 females and 14 males) with ages ranging from newborn to 37 days, weights from 560g to 3060g and skin tones from light to dark. Accuracy (Arms) of the collected convenience samples was 2.7 for the OXY-AF sensor (52 data points were collected in the range of 87%-100%) and 2.7 for the OXY-SE sensor (53 data points were collected in the range of 81%-100%).

***GE TruSignal Technology with GE Oxy-AF (equivalent to TS-AF) and GE Oxy-AP (equivalent to TS-AP) sensors have been validated for motion accuracy in controlled hypoxia studies with healthy non-smoking adult volunteers over the specified saturation SpO_2 range(s). The following motion types were used: mechanically induced 3 Hz tapping motion at an amplitude of 1-2 cm, patient induced non-repetitive rubbing motion, and patient induced non-repetitive hand motion in supine position. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by CO-oximetry. Subjects comprised both adult men and women and spanned a range of skin pigmentations.

****GE TruSignal technology with OxyTip+/GE TruSignal sensors have been validated for pulse rate accuracy over the specified range in bench top testing against a patient simulator. Accuracy was calculated as the root-mean-square (rms) difference between paired pulse rate data recorded with the pulse oximeter equipment and with the patient simulator.

NOTE

Accuracy may vary for some sensors; always check the instructions for the sensor.

GE TruSignal SpO_2 sensor accuracy specifications

NOTE

For detailed information on patient population, sensor site and application refer to GE Trusignal sensor instructions for use.

Part	Sensor model	Part description	SpO_2 range 70% to 100%
SpO_2 - Cable	TS-G3	GE TruSignal Interconnect cable with GE connector	
SpO_2 - Sensor	TS-F2-GE	GE TruSignal Finger Sensor with integrated cable, 2 m	±2 digits without motion
SpO_2 - Sensor	TS-F4-GE	GE TruSignal Finger Sensor with integrated cable, 4 m	±2 digits without motion
SpO_2 - Sensor	TS-F-D	GE TruSignal Finger Sensor	±2 digits without motion
SpO_2 - Sensor	TS-SA-D	GE TruSignal Soft Adult Sensor with integrated cable and D connector, 1 m	±2 digits without motion
SpO_2 - Sensor	TS-SA4-GE	GE TruSignal Soft Adult Sensor with integrated cable and GE connector, 4 m	±2 digits without motion
SpO_2 - Sensor	TS-W-D	GE TruSignal Wrap Sensor	±2 digits without motion
SpO_2 - Sensor	TS-E4-GE	GE TruSignal Ear Sensor with integrated cable, 4 m	±3 digits without motion
SpO_2 - Sensor	TS-E2-GE	GE TruSignal Ear Sensor with integrated cable, 2 m	±3 digits without motion
SpO_2 - Sensor	TS-E-D	GE TruSignal Ear Sensor	±3 digits without motion
SpO_2 - Sensor	TS-SE-3	GE TruSignal Sensitive Skin Sensor	±2 digits without motion
SpO_2 - Sensor	TS-AF-10	GE TruSignal AllFit Sensor, 10/box	±2 digits without motion
SpO_2 - Sensor	TS-AF-25	GE TruSignal AllFit Sensor, 25/box	±2 digits without motion
SpO_2 - Sensor	TS-SP-D	GE TruSignal Soft Pediatric Sensor, 1 m	±2 digits without motion
SpO_2 - Sensor	TS-SP3-GE	GE TruSignal Soft Pediatric Sensor with integrated cable, 3 m	±2 digits without motion
SpO_2 - Sensor	TS-AP-10	GE TruSignal AP Sensor, 10/box	±2 digits without motion
SpO_2 - Sensor	TS-AP-25	GE TruSignal AP Sensor, 25/box	±2 digits without motion

SpO_2 - Accessory	OXY-RTW	OxyTip+ wide replacement tape, adhesive	
SpO_2 - Accessory	OXY-RWL	Foam wrap replacement, large, weight range > 3 kg	
SpO_2 - Accessory	OXY-RWM	Foam wrap replacement, medium, weight range > 3 kg	
SpO_2 - Kit	OXY-BC-5	Bedside clip -5/box	
SpO_2 - Kit	OXY-HB	Replacement headband	
SpO_2 - Accessory	OXY-RWS	Foam wrap replacement, small, weight range < 3 kg	
SpO_2 - Accessory	OXY-RTB	OxyTip+ replacement tape, AllFit Sensor, Bears - 100/box	
SpO_2 - Accessory	OXY-RT	OxyTip+ replacement tape, AllFit Sensor, Blue - 100/box	
SpO_2 - Accessory	OXY-SND	Infant Foam Sandal, use with OxyTip+ Sensitive Skin sensor - 3/box	
OXY- Sensor (No Longer Sold)			
SpO_2 - Cable	OXY-ES3	OxyTip+ Interconnect cable, Ohmeda, 3 m	
SpO_2 - Sensor	OXY-F-UN	Finger Sensor with UN connector, 1 m	±2 digits without motion
SpO_2 - Sensor	OXY-W-UN	Wrap Sensor with UN connector, 1 m	±2 digits without motion
SpO_2 - Sensor	OXY-E-UN	Ear Sensor with UN connector, 1 m	±3 digits without motion
SpO_2 - Sensor	OXY- SE-3	Sensitive Skin Sensor with UN connector, 4 m	±2 digits without motion
SpO_2 - Sensor	OXY-AP-25	Adult/Pediatric Adhesive Sensor - 25/box	±2 digits without motion
SpO_2 - Sensor	OXY-AP-10	Adult/Pediatric Adhesive Sensor - 10/box	±2 digits without motion
SpO_2 - Sensor	OXY-AF-10	AllFit Adhesive Sensor, 0.9 m - 10/box	±2 digits without motion
SpO_2 - Sensor	OXY-F4-GE	Integrated finger sensor, 4 m	±2 digits without motion
SpO_2 - Sensor	OXY-E4-GE	Integrated ear sensor	±3 digits without motion

SpO_2 - Accessory	OXY-F2-GE	OxyTip+ Integrated Finger Care connector 2 m	
SpO_2 - Accessory	OXY-E2-GE	OxyTip+ Integrated Ear Care connector 2 m	

Note: Sensor Accuracy

Because SpO_2 measurements are statistically distributed, only about 2/3 of the measurements can be expected to fall within ±1 Arms of the value measured by a CO-oximeter.

Test methods used to establish SpO_2 accuracy: GE TruSignal SpO_2 measurement have been validated for no motion and motion accuracy in a controlled hypoxia studies with healthy non-smoking adult volunteers over the specified SpO_2 range.

SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by CO-oximetry. Subjects comprised both adult men and women and spanned a range of skin pigmentation.

Sensor light source

Wavelength of SpO_2 probe LEDs	Infrared: 880 to 900 nm (nominal) Red 650 to 670 nm (nominal)	NOTE This information may be useful to clinicians, such as those performing photodynamic therapy.
Maximum energy of SpO_2 probe LEDs	Infrared LED 42 µJ/pulse Red LED 62 µJ/pulse	

Troubleshooting

This section discusses potential difficulties and suggestions for resolving them. If the difficulty persists, contact service or your local Innokas Medical representative.

Problem	Cause	Solution
The heart icon indicates a pulse, but no oxygen saturation or pulse rate values appear on the screen.	• Excessive patient motion may be making it impossible for the SpO_2 function to find a pulse pattern. • The sensor may be damaged. • The patient's perfusion may be too low to allow the SpO_2 function to measure saturation and pulse rate.	• Check the patient. • Check instructions provided by the sensor manufacturer for proper placement. • If possible, keep the patient still; check whether the SpO_2 sensor is applied securely and properly, and replace it if necessary; use the PI value to determine the strength of the signal and move the sensor to a new site; or use an adhesive sensor. • Replace the sensor.

Problem	Cause	Solution
Large sudden changes in the SpO_2 or the pulse rate values. Asterisks or signal quality unstable.	• Excessive patient motion may be making it difficult for the SpO_2 function to find a pulse pattern. • An electrosurgical unit (ESU) may be interfering with performance.	• Check the patient. • If possible, keep the patient still; check whether the sensor is applied securely and properly, and replace it if necessary; use the PI value to determine the strength of the signal and move the sensor to a new site. If an ESU is interfering: • Move the SpO_2 cable as far from the ESU as possible. • Plug the monitor and the ESU into different AC circuits. • Move the ESU ground pad as close to the surgical site as possible. • The sensor may need to be replaced with a new sensor.
The oxygen saturation measurement does not correlate with the value calculated from a blood gas determination.	• The SpO_2 calculation may not have correctly adjusted for the effects of pH; temperature; CO_2; or 2.3-DPG. • Accuracy can be affected by incorrect sensor application or use; intravascular dyes; bright light; excessive patient movement; venous pulsations; electrosurgical interference; and placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line. • The VC150 monitor calculates the displayed values whereas devices such as an anesthesia unit do the actual measurement and analysis.	• Check that calculations have been corrected appropriately for the relevant variable. In general, calculated saturation values are not as reliable as direct laboratory hemoximeter measurements. • If there is excessive light, cover the sensor with opaque material. • Circulation distal to the sensor site should be checked routinely. Refer to the sensor's directions for use supplied with the sensor for requirements on moving the sensor to another site to ensure adhesion, skin integrity, and correct optical alignment. If skin integrity changes, move the sensor to another site. • Try to keep the patient still, or change the sensor site to one with less motion. • Observe all instructions, warnings, and cautions in this manual and in the directions for use of the sensor. • If a device such as an anesthesia unit displays different values, use that information instead.
A valid SpO_2 signal was present but has disappeared.	• An NIBP determination on the same limb is in progress.	• Check the patient. • An alarm message code appears on the screen, and the audible alarm will sound immediately. • Move the sensor to the arm that is not connected to a blood pressure cuff.
An error message for sensor replacement appears.	• The sensor or cable may be the wrong type or defective, the cabling may be improperly connected.	• Check the patient. • If possible, keep the patient still; check whether the proper sensor/cable is applied securely and properly, and replace it if necessary. • Disconnect and reconnect the sensor.

Problem	Cause	Solution
An error message for sensor connection problem appears.	• The sensor is not completely connected. The interconnect cable or sensor wiring is faulty. • Ensure the appropriate sensor and cable are being used.	• Check the patient. • Check the sensor connection to the interconnect cable and the interconnect cable connection to the monitor. Then, if needed, replace the sensor or the interconnect cable. • Use only compatible sensors and cables.

8 Masimo SpO_2

Description

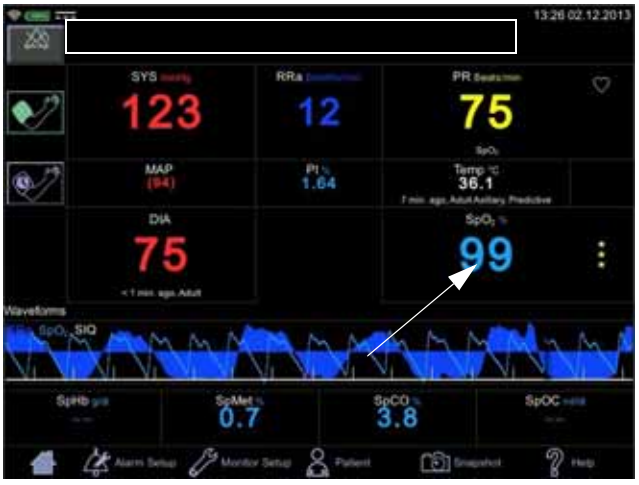
The SpO_2 parameter in the monitor is available in three different technologies:

- GE TruSignal
- Nellcor OxiMax™
- Masimo rainbow® SET®

The SpO_2 technology logo on the left side of the monitor, above the physical connector, will disclose which technology the monitor is equipped with. If you want to use a different SpO_2 technology than your monitor is currently equipped with, contact service to discuss the procedure. Use of Masimo rainbow® SET® parameters or Masimo RRa requires licenses that can be purchased separately and may need specific accessories.

The SpO_2 function is calibrated to read functional arterial oxygen saturation. When a suitable SpO_2 sensor is connected to the monitor and to the patient, the measurement values will be shown on the screen. Pulse rate derived from SpO_2 appears in the ***PR (Pulse Rate)*** window and updates continuously. The primary source of pulse rate is always SpO_2, i.e., if SpO_2 is measuring when an NIBP determination is completed, the pulse rate derived from NIBP is not displayed. A tone sounds at a rate corresponding to the pulse rate and at a pitch corresponding to the SpO_2 saturation level. The pitch is highest at 100% oxygen saturation, and it continuously decreases as the saturation level falls.

> CAUTION
> The pulse rate derived from SpO_2 is a value calculated from oxygen levels. The pulse rate is not equal to the patient's actual heart rate.



Audible and visual alarms occur when SpO_2 levels are outside the alarm limits. and the monitor is in monitoring mode. When a parameter status alarm occurs, an alarm message appears at the top of the screen (rectangle in the image above).

SpO_2 safety

WARNINGS

Many factors may cause inaccurate readings and alarms, decreased perfusion, and/or low signal strength:

Interfering substances:

- Carboxyhemoglobin may erroneously increase SpO_2 readings.
- Methemoglobin (MetHb) usually represents less than 1% of the total Hgb, but in the case of methemoglobinemia that can be congenital or induced by some IV dyes, antibiotics (such as sulphas), inhaled gases, etc., this level increases sharply. Methemoglobin may cause inaccurate SpO_2 readings.
- Intravascular dyes (such as indocyanine green, methylene blue, etc.) at certain concentrations may cause inaccurate SpO_2 readings and/or decreased perfusion and corresponding signal strength, potentially causing inaccurate SpO_2 readings.
-Nail polish and artificial nails may cause inaccurate readings.

Physiological characteristics:

Some physiological characteristics may cause decreased perfusion and/or low signal strength and may potentially cause inaccurate SpO_2 readings:

- Cardiac arrest, hypotension, shock, severe vasoconstriction, severe anemia, hypothermia, venous pulsations, congestions, darkly pigmented skin, ventricular septal defects (VSDs)

Environmental conditions:

Some environmental conditions may cause interference or artifact and may potentially cause inaccurate SpO_2 readings.

- Excessive ambient light sources (e.g., infrared heat lamps, strobe lights, bilirubin lights, direct sunlight, operating room lights). To prevent such interference, cover the sensor with opaque material.
- Electrical interference/Electrosurgery
- Defibrillation - May cause inaccurate reading for a short amount of time.
- Excessive patient/sensor motion. Artifact can simulate an SpO_2 reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

Sensor placement:

- Sensor placement on the same extremity as a blood pressure cuff, arterial catheter or intravascular line; or arterial occlusion proximal to the sensor; or a sensor below the heart level may cause decreased perfusion and/or low signal strength and potentially cause inaccurate SpO_2 readings.
- Poor sensor fit may cause decreased or low signal strength and potentially cause inaccurate SpO_2 readings.
- Do not allow tape to block the sensor light emitter and detector as this may cause decreased perfusion and/or low signal strength and potentially cause inaccurate SpO_2 readings.
- Before using the Masimo sensor, carefully read the Masimo sensor instructions for use.

WARNING

As with any wrap or clip-on sensor, pressure is exerted. Be cautious in using a wrap or clip-on sensor on patients with compromised circulation (e.g., peripheral vascular disease or vasoconstricting medications).

Allow sensor and cable to dry completely after cleaning. Moisture and dirt on the connector can affect the measurement accuracy.

Inaccurate SpO_2 data can result if a sensor is past its useful life. Therefore, re-evaluate the measurement periodically by performing additional assessment of the patient equipment, including consideration of use of alternate monitoring methods such as direct measurement of arterial oxyhemoglobin saturation (SaO_2).

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs, then check for conditions that may cause inaccurate SpO_2 readings. If the problem is still not resolved, check the SpO_2 module or sensor for proper functioning.

Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high.

If the perfusion index falls below 0.02%, SpO_2 values will not be displayed.

A pulse oximeter or CO-oximeter should not be used as an apnea monitor.

If you deactivate the ***SpO2 Sensor Off*** alarm, keep the patient under close surveillance.

Single-use products are not designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, and cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization and/or reuse.

Clean the surface of the probe before and after each patient use.

Do not loop the sensor cable into a tight coil or wrap around the device, as this can damage the sensor cable.

CAUTION

Do not sterilize reusable sensors by irradiation, steam, or ethylene oxide. See the sensor manufacturer's instructions for cleaning, sterilization, or disinfecting methods.

CAUTIONS

Do not place SpO_2 sensor on patient during magnetic resonance imaging (MRI). Adverse reactions include potential burns to patients as a result of contact with attachments heated by the MRI radio frequency pulse, potential degradation of the magnetic resonance image, and potential reduced accuracy of SpO_2 measurements. Always remove oximetry devices and attachments from the MRI environment before scanning a patient.

Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

Placing a sensor distal to an arterial line may interfere with adequate arterial pulsation and compromise the measurement of SpO_2.

The sensor disconnect error message and associated alarm indicate that the sensor is either disconnected or the wiring is faulty. The user should check the sensor connection and, if necessary, replace the sensor, interconnect cable, or both.

Placing a sensor on a polished or an artificial nail may affect accuracy.

Patient safety:

Do not place any clip-on sensor in a patient's mouth, on their nose or toes, on their thumb, or across a child's foot or hand.

Prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. Observe the sensor site frequently to assure adequate distal circulation. Sensor sites should be checked at least every 2 hours and rotated at least every 4 hours. Refer to instructions supplied with sensor.

If the sensor is not applied properly, the patient's skin could be injured or the ability of the monitor to measure oxygen saturation could be compromised. For example, a clip-on sensor should never be taped shut. Taping the sensor could damage the patient's skin or impair the venous return, thus causing venous pulsation and inaccurate measurement of oxygen saturation.

Excessive pressure from the sensor may cause necrosis of the skin.

Monitor performance:

Place the sensor so that the LEDs and the photodiode are opposite each other.

Monitor performance:

When an SpO_2 sensor is located on the same limb as the NIBP cuff, SpO_2 readings will not be valid while the cuff is inflated. If valid SpO_2 readings are required during the entire blood pressure determination, attach the SpO_2 sensor to the limb opposite the one with the blood pressure cuff.

NOTES

- A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease pulse rate.
- SpO_2 and pulse rate values are filtered by an averaging technique, which determines how quickly the reported values respond to changes in the patient's saturation. Increased averaging time effects time to alarm for SpO_2 saturation and pulse rate limits.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- Software development, software validation, and risk and hazard analysis have been performed to a registered quality system.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter cannot distinguish between oxyhemoglobin and dyshemoglobins.
- Poor perfusion may affect the accuracy of measurement, especially when using an ear sensor.
- Check that the red light is lit in the sensor.
- Check that the waveforms (if enabled in monitor setup) and parameter values are displayed when the sensor is connected to the patient.
- Additional information specific to the Masimo sensors compatible with the VC150, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

SpO_2 on the screen

When SpO_2 is not receiving measurement data, a double dash (--) appears in this window. When the sensor switches to operation mode, the SpO_2 parameter starts to receive data. If the data is valid, the derived SpO_2 value appears in this window and updates continuously. The values are displayed in %.

SpO_2 values are displayed on the lower right side of the monitor screen. The SpO_2 and PI values are displayed in cyan color by default. This can be changed in configuration mode. If the monitor is providing the temperature measurement the SpO_2 value will be located under the displayed temperature value.

The SpO_2 field consists of the SpO_2 label, the measured value in the middle and the measurement site underneath the parameter value. The measurement site choices are: ***Finger***, ***Nose***, ***Toe***, ***Earlobe***. The site name ***Other*** can be used to indicate it was none of the above. The default site is ***None***. Next to the measured value is a column of asterisks representing signal quality, as well as upper and lower limits for the SpO_2 value.

If the sensor is detached from the patient, the ***SpO_2*** status switches to 'off patient' and displays --.

NOTES

If pulse rate data from SpO_2 data is available, the ***Pulse Rate*** window is associated with this parameter and a heart symbol is displayed on screen. Refer to "Pulse rate" on page 10-1 for more information.

If accuracy for a SpO_2 derived parameter is not yet guaranteed, a dimmed value is displayed on screen.

Perfusion index measurement

The perfusion index (PI) measurement is a clinical tool that provides a dynamic numeric reflection of perfusion at the sensor site. PI is a relative value that varies from patient to patient. The perfusion index value appears in its own field under the label PI. The user can use the PI value to compare the strength of the pulse signal at different sites on a patient in order to locate the best site for the sensor, i.e., the site with the strongest pulse signal.

Signal quality values are mathematically calculated perfusion values represented by asterisks.[1] The SpO_2 signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of a Low Signal Quality message. The more asterisks there are the better the signal quality. The better the arterial blood flow is, better signal quality is obtained. A strong pulse signal increases the validity of SpO_2 and pulse rate data.

[1]In Masimo equipped monitors signal quality is represented by asterisks, however signal quality is not associated with the perfusion value. Refer to Signal IQ waveform (Masimo) section for further information regarding Masimo signal quality representation.

Signal IQ (SIQ)

The Signal IQ provides an indicator of the assessment of the confidence in the displayed SpO_2 value. The SpO_2 SIQ can be also used to identify the occurrence of a patient's pulse.

With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. Shown as a vertical line, the SpO_2 SIQ coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Signal IQ identifies the timing that the algorithms have determined for the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the SpO_2 SIQ.

The height of the vertical line of the SpO_2 SIQ provides an assessment of the confidence in the measurement displayed. A high vertical bar indicates higher confidence in the measurement. A small vertical bar indicates lower confidence in the displayed measurement. When the Signal IQ is very low, this suggests that the accuracy of the displayed measurement may be compromised.

When parameters are dimly lit, proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the monitor to maintain accurate readings. Misalignment of the sensor's emitter and detector can result in smaller signals and cause erroneous readings.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or an episode of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. Interruption, for example, may occur while lifting or crossing their legs during a diaper change.
- After performing the above, if the parameter remains dimly lit frequently or continuously, obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.

VC150 displays the signal quality also with 0 to 3 asterisks next to the SpO_2 parameter.

Changing the SpO_2 alarm limits

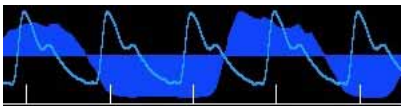
SpO_2 alarm limit adjustments can be set either A) by entering upper and lower limit values directly in a limit box on the home screen as instructed in "Using the numeric keypad" on page 3-12 or B) by adjusting limit values in the ***Alarm Setup*** screen as instructed in "Procedure for testing alarms" on page 3-11.

Pleth

The Plethysmographic waveform (Pleth) represents a real-time waveform for the relative SpO_2 pulsatile amplitude. The Pleth waveform is always automatically scaled to fit the window for the best display quality. The waveform uses the same color as the SpO_2 field.

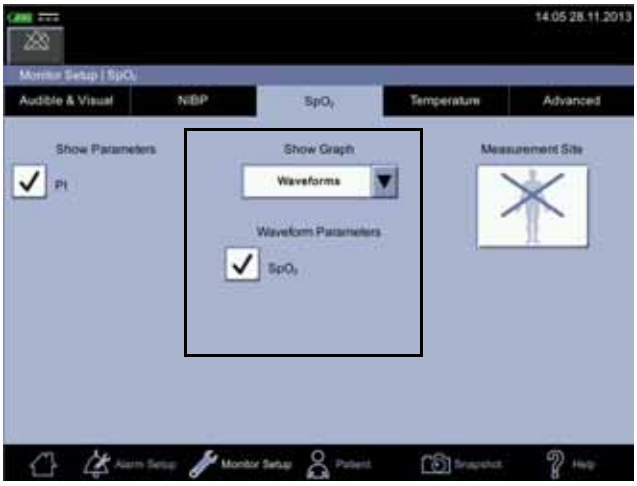
Graphic representation of RRa (Masimo)

The RRa waveform data provides users with a visual indication of respiratory activity. This requires an acoustic sensor. The RRa curve is slightly asymmetrical as the airflow sounds generated in the upper airway are different during different stages of breathing. Graphic representation can be selected in ***Monitor Setup > SpO_2***. The RRa curve can be displayed simultaneously with the Pleth curve.



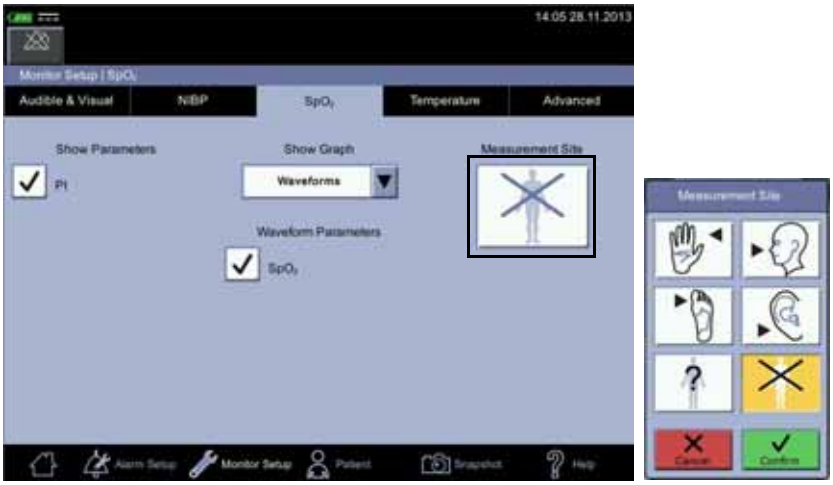
Pleth waveform settings

Select ***Waveforms*** in the drop-down menu under ***Show Graph*** in the ***Monitor Setup > SpO_2*** to display the ***Pleth***. Also select parameters to be displayed as waveforms (availability depends on which SpO_2 technology the monitor is equipped with and which options have been purchased).



SpO_2 measurement site

For documentation purposes, you can select the measurement site for SpO_2 in ***Monitor Setup > SpO_2*** before you start measuring SpO_2. A pop-up screen with the following images will appear: ***Finger***, ***Nose, Toe, Earlobe, Other*** or ***None***. It does not matter whether the site is on the left or right side of the patient. After the site is selected, it will be displayed on the home screen in the SpO_2 parameter window. The selection can be changed between the measurements. Admitting a new patient will reset the selection of the measurement site.



SpO_2 procedure

1. Check the label on the monitor to determine which SpO_2 technology the monitor is using. To assure optimal performance, use only accessories that are intended for that technology. If you cannot read the label, ask the nurse manager or service which SpO_2 technology is used.
2. Select a sensor that is appropriate for the patient, the clinical situation and for the SpO_2 technology used. Do not use an adult sensor on a neonatal/ pediatric patient and vice versa.

   WARNING
   Do not use a sensor, cables, or connectors that appear damaged or with exposed electrical contacts.

   Never repair a damaged sensor or cable; never use a sensor or cable repaired by others.

3. Ensure the VC150 is connected to power or the battery is fully charged.
4. Ensure the VC150 is powered on. The monitor has to display clinical mode and SpO_2 parameter on screen.
5. Connect an interface cable to the monitoring system sensor port.
6. Follow the manufacturer's guide to plug in the SpO_2 cable into the monitor and apply the proper SpO_2 sensor. The VC150 reports the appropriate sensor type in the message field when it detects the sensor. If you use RRa sensor, place it as instructed in the direction of use of the sensor. Refer also to "Acoustic Sensor placement" on page 8-11. If RRa sensor is used: contact Innokas Medical service to upgrade the VC150 if the RRa parameter does not appear on the screen.
7. Select the measurement site in ***Monitor Setup > SpO_2***, if desired. A shortcut: Select SpO_2 parameter area on the home screen to jump to the ***SpO_2*** screen.
8. *Following the directions for use supplied with the sensor*, apply the sensor to the patient.

9. Proceed with monitoring. SpO_2 measurements run continuously and can run simultaneously with other measurements.
10. Clean the sensor as instructed in "Cleaning SpO2 sensors" on page B-8".

SpO_2 sounds

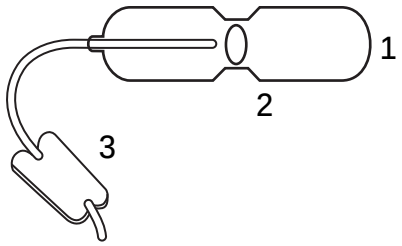
The monitor provides an audible tone for each pulse detected by the SpO_2 parameter. The pitch of the audible tone is directly related to the calculated saturation value. As the saturation value increases, the pitch rises. As the saturation value decreases, the pitch frequency goes down. This audible tone is silenced while an alarm sounds or the ***Day Volume*** or ***Night Volume*** is set to ***0***. Refer to "Audible & Visual" on page 3-19 in this section.

Acoustic sensors

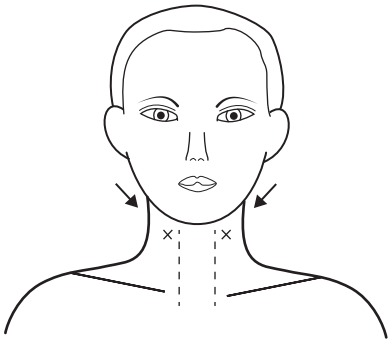
Masimo SpO_2 technology uses acoustic sensors to capture breathing sounds that are relayed to the monitor and transformed into a respiration rate. A Dual rainbow® cable with two sensors at the end of the cable is connected to the monitor. Then place the RRa sensor over the patient's airway on either side of their neck and the other on some part of the body for SpO_2 measurement. Respiration rate is provided only if SpO_2 data is also measured.

Acoustic Sensor placement

The Acoustic sensor has a small black arrow on the front (item 1 in figure below), when placing the sensor the black arrow should point forward to the anterior of subject's body.



1. Ensure placement site is hair-free, clean of debris, and dry prior to sensor placement. Use an alcohol swab to clean the neck area, if needed.
2. The sensor pad (item 2 in the figure above) should be placed to either side of the larynx, in the area just above the thyroid cartilage and below the jaw line (see figure below). Ensure that there are no skin folds under the sensor pad.



NOTE

For pediatric subjects that have limited neck space, the sensor may be placed on the right side of chest (dotted oval in the image above), underneath clavicle. The sensor should not be touching the clavicle.

3. Place sensor tape on skin.
4. Gently press on sensor tape from center outward so adhesive forms a good contact with patient's skin.
5. Ensure there are no skin folds or air gaps under sensor pad.
6. Remove the release liner from the anchor pad and place the anchor pad on patient’s side of the neck; route the sensor cable in front of patient. Do not place anchor pad on clothing.

Alarms

If the SpO_2 parameter determines the signal to be valid, SpO_2 values are displayed. In case the signal quality deteriorates to a questionable level, the ***SpO_2*** or ***Pulse Rate*** values disappear from the screen and an alarm message for lost pulse signal is generated.

Alarm timer

The user can select between monitoring mode and spot-check mode. In spot-check mode, clinical alarms and related functions are not available. If an SpO_2 measurement continues for 5 minutes uninterrupted, the monitor automatically moves from spot-check mode to monitoring mode. The alarms will be enabled in monitoring mode.

If the probe is taken off and you want to measure the same patient without alarms, select spot-check mode again.

NOTE

To prevent misuse of the device, duration of the SpO_2 spot-check mode is limited to 5 minutes.

If SpO_2 is unable to be measured for some reason, then a technical status message that indicates the reason for not measuring will appear below the parameter value. If an abnormal technical status remains for ten seconds, then a low priority alarm is created.

An abnormal technical status will create an alarm in both spot-check and monitoring mode.

Compatible Masimo accessories

All approved and VC150 compliant accessories are listed in the VC150 supplies and accessories document. Use only accessories listed in that document. If you already have an accessory that you want to use with the VC150 monitor, check whether it is listed in that document. If it not listed, do not use it with the VC150 monitor.

Masimo rainbow® SET® SpO_2 and special features

Masimo Signal Extraction Technology (SET) pulse oximetry utilizes parallel engines and adaptive digital filtering. The Masimo SET signal processing algorithm, Discrete Saturation Transform® (DST®), in parallel with Fast Saturation Transform (FST®), identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

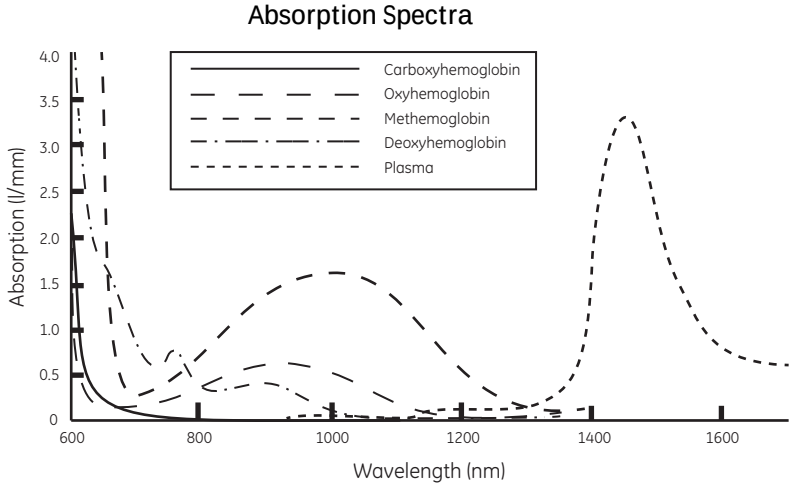
Functional oxygen saturation (SpO_2) of arterial blood is noninvasively and continuously monitored using pulse oximetry technology from Masimo rainbow® SET®. Functional SpO_2 is the ratio of oxygenated hemoglobin to hemoglobin that is capable of transporting oxygen. This ratio, expressed as a percentage, is shown in the ***SpO_2*** window, which is continually updated. If the signal quality is low for any Masimo parameter, the corresponding measurement value is dimmed. This is typical when the sensor is connected to a patient and a new measurement begins. As the signal quality is determined to be reliable, the values turn to normal brightness.

The SpO_2 parameter is indicated for use in continuous, noninvasive monitoring of functional oxygen saturation and in providing pulse rate data as a component of the monitor. This device is not designed, sold, or intended for use except as indicated.

rainbow Pulse CO-Oximetry Technology

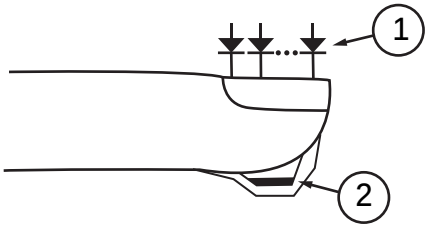
rainbow Pulse CO-Oximetry technology is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).
2. The amount of arterial blood in tissue changes with pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.



Masimo rainbow sensors use a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

Masimo rainbow sensors utilize various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the Masimo circuit board for calculation.



1. Light Emitting Diodes (LEDs) (7 or more wavelengths)
2. Detector

Once the Masimo board receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO_2 [%]), blood levels of carboxyhemoglobin (SpCO [%]), methemoglobin (SpMet [%]), total hemoglobin concentration (SpHb [g/dL]) and pulse rate (PR). The SpCO, SpMet and SpHb measurements rely on a multi-wavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood.

In an ambient temperature of 35° C the maximum skin surface temperature has been measured at less than 106° F (41° C), verified by Masimo sensor skin temperature test procedure.

Pulse CO-Oximetry vs. Drawn Whole Blood Measurements

When SpO_2, SpCO, SpMet, and SpHb measurements obtained by Masimo rainbow technology (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results.

The blood gas and/or laboratory CO-Oximetry measurements may differ from the SpO_2, SpCO, SpMet, SpHb, and SpOC measurements made by Masimo rainbow technology. Any comparisons should be simultaneous, meaning the measurement on the device should be noted at the exact time that blood is drawn.

In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (PO_2) and saturation, such as: pH,temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. In the case of SpCO, different results are also expected if concentration of methemoglobin in the blood gas sample is abnormal (greater than 2% for methemoglobin concentration).

High levels of bilirubin may cause erroneous SpO_2, SpMet, SpCO, and SpHb readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin, and methemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of SpO_2, SpCO, SpMet, SpHb, and SpOC may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn whole blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

Measurements with Low Signal IQ should not be compared to laboratory measurements.

General Description for Total Arterial Oxygen Content (CaO_2)

Oxygen (O_2) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content (CaO_2) and is measured in units of ml O_2/dL blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen*. The oxygen content is determined mathematically as:

$CaO_2 = 1.34$ (ml O_2/g Hb) x Hb (g/dL) x HbO_2 + PaO_2 (mm Hg) x (0.3 ml O_2/100 mm Hg/dL)

Where HbO_2 is the fractional arterial oxygen saturation and PaO2 is the partial pressure of arterial oxygen.

For typical PaO_2 values, the second part of the above equation (PaO_2 [mm Hg] x [0.3 ml O2/ 100 mm Hg/dL]) is approximately 0.3 ml/dL. Furthermore, for typical carboxyhemoglobin and methemoglobin levels, the functional saturation (SpO_2) as measured by a pulse oximeter is given by:

$SpO_2 = 1.02 \times HbO_2$

**Martin, Laurence. All You Really Need to Know to Interpret Arterial Blood Gases, Second Edition. New York: Lippincott Williams & Wilkins, 1999.*

General Description for SpOC

The above approximations result in the following reduced equation for oxygen content via the Pulse CO-Oximeter:

SpOC (ml/dL*) = 1.31 (ml O_2/g Hb) x SpHb (g/dL) x SpO_2 + 0.3 ml/dL

*When ml O_2/g Hb is multiplied by g/dL of SpHb, the gram unit in the denominator of ml/g cancels the gram unit in the numerator of g/dL resulting in ml/dL (ml of oxygen in one dL of blood) as the unit of measure for SpOC.

Description for Carboxyhemoglobin (SpCO)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin concentration (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through an instrument patient cable.

The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

Successful Monitoring for SpCO

A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

General Description for Total Hemoglobin (SpHb)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make its SpHb measurement. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adult and pediatric patients.

The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as measurement of total hemoglobin concentration.

Successful Monitoring for SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

General Description for Methemoglobin (SpMet)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through a patient cable.

The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpMet.

Successful Monitoring for SpMet

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site).

Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

WARNINGS

Masimo labeled monitors are compatible only with Masimo sensors and cables, which are available from your Innokas Medical representative or from Masimo or its local representative. Other oxygen transducers (sensors) may cause improper SpO_2 performance.

Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis.

A pulse CO-oximeter should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.

For measurements of high or low SpHb readings, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.

WARNINGS

SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.

For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present.

NOTE! High levels of SpCO may occur with a seemingly normal SpO_2. When elevated levels of SpCO are suspected, laboratory analysis (CO-oximetry) of a blood sample should be performed.

For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-oximetry of a blood sample should be performed.

Interfering substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.

Hemoglobin synthesis disorders may cause erroneous SpHb readings.

Elevated levels of total bilirubin may lead to inaccurate SpO_2, SpMet, SpCO, SpHb, and SpOC measurements.

Motion artifact may lead to inaccurate SpMet, SpCO, SpHb, SpOC measurements.

Severe anemia may cause erroneous SpO_2 readings.

Very low arterial oxygen saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements.

With very low perfusion at the monitored site, readings may read lower than core arterial oxygen saturation.

Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.

If the sensor is wrapped too tightly or supplemental tape is used, venous congestion/pulsations may occur, causing erroneous readings.

Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from the monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in bed with arm dangling to the floor).

Venous pulsations may cause erroneous readings (e.g. tricuspid valve regurgitation).

WARNINGS

Loss of pulse signal can occur when:

- Sensor is too tight.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- There is arterial occlusion proximal to the sensor.
- The patient is in cardiac arrest or is in shock.

The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.

Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

Avoid placing the sensor on any extremity with arterial catheter or blood pressure cuff.

High intensity extreme lights (including pulsating strobe lights) directed on the sensor may not allow the pulse CO-oximeter to obtain readings.

The pulse CO-oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

Before use, carefully read the sensor's directions for use.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor's directions for use to ensure skin integrity and correct positioning and adhesion of the sensor.

To avoid cross contamination only use Masimo single use sensors on the same patient.

Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide. See the cleaning instructions in the directions for use for the Masimo re-useable sensors.

SpO_2 monitoring is required when monitoring RRa (acoustic respiration).

Excessive ambient noise may affect the accuracy of the respiration rate reading from the acoustic respiration sensor.

Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.

For SpHb, the VC150 should be considered an early warning device. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

WARNINGS

Variation in hemoglobin measurements may be profound and may be affected by sample type, body positioning, as well as other physiological conditions. As with most hemoglobin tests, VC150 test results should be scrutinized in light of a specific patient's condition. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data.

Inaccurate SpHb and SpOC readings may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Difference between patient's finger skin and finger core temperature
- Hemoglobin synthesis disorders
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's
- Elevated altitude
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

Inaccurate SpCO and SpMet readings may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion
- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact
- SpCO readings may not be provided if SpO_2 readings are less than 90%
- SpCO readings may not be provided if SpMet readings are greater than 2%

WARNING

Inaccurate SpCO readings can be caused by:

- Levels of methemoglobin approximately 1.5% or above

Inaccurate respiration rate measurements may be caused by:

- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation
- Excessive ambient or environmental noise
- Improper sensor placement

The Desat Index alarm is intended as an adjunct rather than in place of the Low Saturation alarm.

CAUTIONS

Do not use the pulse CO-oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The pulse CO-oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

If using pulse CO-oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.

Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

Circulation distal to the sensor site should be checked routinely.

A functional tester cannot be utilized to assess the accuracy of the pulse CO-oximeter or any sensors.

Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.

The dual rainbow® cable is designed to directly interface with validated rainbow® acoustic monitoring enabled devices or with validated rainbow® acoustic monitoring enabled multiparameter monitors.

CAUTIONS

Failure to properly connect a dual rainbow® cable to the rainbow® acoustic monitoring enabled device or multiparameter monitor may result in intermittent readings, inaccurate results or no reading.

If the ***SpO_2 Perfusion Low*** message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

rainbow Acoustic Monitoring (RAM) Technology

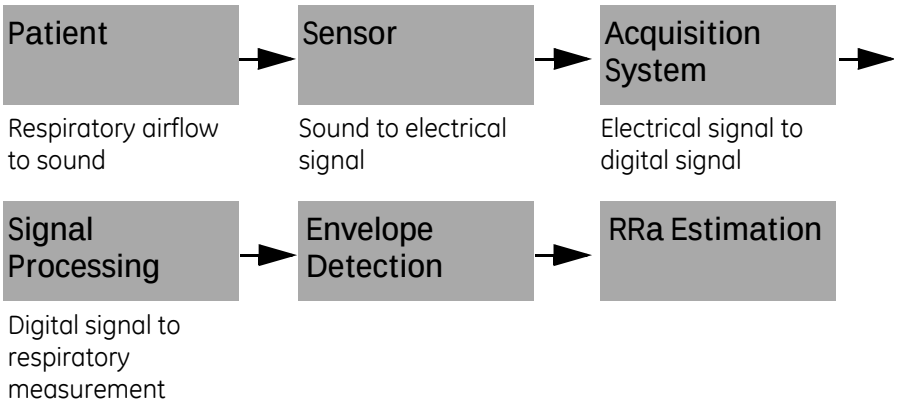
rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor translates airflow sounds generated in the upper airway to an electrical signal that can be processed to produce a respiration rate, measured as breaths per minute.

Respiratory sounds include sounds related to respiration such as breath sounds (during inspiration and expiration), adventitious sounds, cough sounds, snoring sounds, sneezing sounds, and sounds from the respiratory muscles [1].

These respiratory sounds often have different characteristics depending on the location of recording [2] and they originate in the large airways where air velocity and air turbulence induce vibration in the airway wall. These vibrations are transmitted, for example, through the lung tissue, thoracic wall and trachea to the surface where they may be heard with the aid of a stethoscope, a stethoscope, a microphone or more sophisticated devices.

rainbow Acoustic Monitoring Architecture

The following figure illustrates how a respiratory sound produced by a patient can be turned into a numerical measurement that corresponds to a respiratory parameter.



Patient

The generation of respiratory sounds is primarily related to turbulent respiratory airflow in upper airways. Sound pressure waves within the airway gas and airway wall motion contribute to the vibrations that reach the body surface and are recorded as respiratory sounds.

Although the spectral shape of respiratory sounds varies widely from person to person, it is often reproducible within the same person, likely reflecting the strong influence of individual airway anatomy [2-6].

Sensor

The sensor captures respiratory sounds (and other biological sounds) much like a microphone does. When subjected to a mechanical strain, (e.g., surface vibrations generated during breathing), the sensor becomes electrically polarized.

The degree of polarization is proportional to the applied strain. The output of the sensor is an electric signal that includes a sound signal that is modulated by inspiratory and expiratory phases of the respiratory cycle.

Acquisition System

The acquisition system converts the electric signal provided by the sensor into a digital signal. This format allows the signal to be processed by a computing device.

Signal Processing

The digital signal produced by the acquisition system is converted into a measurement that corresponds to the respiratory parameter of interest. As shown in the previous figure, this can be performed by, for example, determining the digital signal envelope or outline which in turn may be utilized to determine the respiratory rate. In this way, a real-time, continuous breath rate parameter can be obtained and displayed on a monitor which, in many cases, may be real-time and continuous.

The respiratory cycle envelope signal processing principle is similar to methods that sample airway gasses and subsequently determine a respiratory rate.

[1] A.R.A. Sovijärvi, F. Dalmasso, J. Vanderschool, L.P. Malmberg, G. Righini, S.A.T. Stoneman. Definition of terms for applications of respiratory sounds. Eur Respir Rev 2000; 10:77, 597-610.

[2] Z. Moussavi. Fundamentals of respiratory sounds analysis. Synthesis lectures on biomedical engineering #8. Morgan & Claypool Publishers, 2006.

[3] Olsen, et al. Mechanisms of lung sound generation. Semin Respir Med 1985; 6: 171-179.

[4] Pastercamp H, Kraman SS, Wodicka GR. Respiratory sounds – Advances beyond the stethoscope. Am J Respir Crit Care Med 1977; 156: 974-987.

[5] Gavriely N, Cugell DW. Airflow effects on amplitude and spectral content of normal breath sounds. J Appl Physiol 1996; 80: 5-13.

[6] Gavrieli N, Palti Y, Alroy G. Spectral characteristics of normal breath sounds. J Appl Physiol 1981; 50: 307-314.

Masimo rainbow® SET® SpO_2 configuration

There are multiple configuration settings associated with this parameter. Refer to the following table for details and then configure as necessary.

Masimo rainbow® SET® feature	Description
Acoustic Resp Rate RRa	This feature uses acoustic technology to continually measure a patient's respiration rate based on airflow sounds generated during the breathing cycle of inspiration and expiration.
Desat Index 3D Alarm	This feature alerts for an increasing quantity of smaller desaturations that may not exceed the low SpO_2 alarm threshold and that may provide an early indication that the patient's respiratory status is declining. The user enters the period of time over which to look at desaturations, desired delta threshold (% from baseline), and number of desaturations before being alerted. Current number of desaturations is displayed by ***Desaturation Index***. The number of ***Desat Occurrences*** can be reset by 1) adjusting the ***Desat Threshold,*** or 2) removing the sensor from the patient or the monitor. Options: • ***Desat Occurrences*** can range from 1 to 24. • ***Desat Threshold*** range change from 2-10% in 1% increments. • ***Desat Time period*** range from 1 to 4 hours in 1 hr increments. Configure in ***Alarm Setup*** or ***Monitor Setup > Advanced > Default Setup > Alarm Defaults***.
FastSat Algorithm	FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend. FastSat is always on when 2 - 4 and 4 - 6 averaging modes are activated. FastSat is not recommended for routine use as the increased fidelity of this mode may also increase the frequency of alarms caused by rapid but transitory changes in SpO_2. FastSat enables rapid response to, and display of, fast changes in SpO_2 by giving priority to the most recent data.
Oxygen Content SpOC	During some seizures, oxygen levels may drop to dangerous levels. SpOC is a non-invasive measure of the total oxygen content present in the blood.
Perfusion Index (PI)	The Perfusion Index (PI) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. PI thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

Masimo rainbow® SET® feature	Description
Perfusion Index Averaging	This feature allows you to select the desired level of visibility to subtle variations in the measured value. Depending on the patient acuity and area of care, shorter averaging times are sometimes preferred (trauma) over longer averaging times (neonates) and vice versa. This benefits patient care by fine tuning PI responsiveness to physiological changes. Options: ***Short***, ***Long***. Configure in ***Monitor Setup > Advanced > Default Setup > Measurement Settings***.
PI Delta 3D Alarm	This feature alerts you to changes in perfusion. When enabled, the PI Delta alarm notifies you if the patient's perfusion index (PI) declines by a user-selectable percentage from the patient's baseline PI value over a user-selectable time period. This alarm is intended to help you identify early changes in peripheral perfusion that may otherwise be difficult to identify and are often missed despite being a potentially valuable indicator of illness severity. The PI Delta Index baseline is continually being calculated by the board while the sensor is on a patient. NOTE PI Delta 3D Alarm is a latching alarm that is not automatically dismissed when a new patient is admitted. The alarm must always be acknowledged by selecting the alarm message. Options: • ***PI Delta Range*** from 10% to 99% in 1% increments. • ***PI Delta Time Period*** range from ***NONE***, to ***1***, ***5***, and ***30 min***, plus ***1***, ***4***, ***8***, ***12***, ***24***, ***36***, and ***48 hours***. • ***Set Baseline PI*** to establish a level that PI Delta Index values are measured against. Configure in ***Alarm Setup*** or ***Monitor Setup > Advanced > Default Setup > Alarm Defaults***.
Rapid Desat Alarm Threshold	This setting is intended to allow the clinician to feel comfortable setting longer alarm delay periods - to minimize nuisance alarms for real but transitory events - by overriding the alarm delay period when rapid desaturations exceed the alarm limit threshold by a larger, user-selectable percentage. This setting cannot be used with SpO_2 alarm delay. The Rapid Desat Alarm Threshold feature includes a built-in alarm delay for 15 seconds. For example, if ***Rapid Desat Alarm Threshold*** is set at 5%, the SpO_2 percentage can fall 5% below the lower limit for less than 15 seconds. If the SpO_2 percentage falls lower than 5% down from the lower limit, an alarm will occur immediately. Also if SpO_2 percentage remains 0.1-5% down from the lower limit for over 15 seconds an alarm will occur immediately. Options: ***5%***, ***10%***, ***Off***. Configure in ***Alarm Setup*** or ***Monitor Setup > Advanced > Default Setup > Alarm Defaults***.

Masimo rainbow® SET® feature	Description
RRa Alarm Delay	Many changes in RRa are real but transitory and in some cases, such transitory changes, may not require clinical action or intervention ("non-actionable"). This feature allows you to set an audible alarm delay of a certain number of seconds before sounding an RRa audible alarm. The delay setting only affects RRa audible alarm limits. This option allows you to require that the RRa value exceeds the alarm limit for a user-selectable duration before an audible alarm, minimizing the risk that caregivers will become desensitized to audible alarms due to non-actionable events. Options: *0*, *10*, *15*, *30*, *60* seconds. Configure in *Alarm Setup* or *Monitor Setup > Advanced > Default Setup > Measurement Settings*.
RRa Averaging Time	This feature allows you to select the desired level of visibility to subtle variations in the measured value. Options: *10*, *20*, *30*, *60* seconds (approximately). Configure in *Monitor Setup > Advanced > Default Setup > Measurement Settings*.
RRa Freshness Timeout	This feature allows you to adjust RRa alarms to accommodate various breathing patterns (talking, eating, etc.). The feature refers to the maximum amount of time the monitor will display the last known RRa value before the next measurement becomes available or an alarm condition is triggered. When the desired freshness timeout is set, the monitor will provide audible and visual notification if the freshness time is exceeded. Options: *0*, *1*, *5*, *10*, *15* minutes. Configure in *Monitor Setup > Advanced > Default Setup > Measurement Settings*.
RRa Pause Time	This feature allows you to adjust the alarm system to accommodate various breathing patterns by setting the maximum pause time. The monitor will provide audible and visual notification to the user if the pause time is exceeded. Options: *15*, *20*, *25*, *30*, *35*, *40* seconds. Configure in *Monitor Setup > Advanced > Default Setup > Measurement Settings*.
Smart Tone	Smart Tone affects pulse beep and allows a pulse beep to continue even when the Pleth waveform is corrupt due to motion. When Smart Tone is off, the pulse beep is suppressed during signs of motion.
SpCO	Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin concentration (SpCO) in arterial blood. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants.
SpHb	Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adult and pediatric patients.

Masimo rainbow® SET® feature	Description
SpHb Arterial / Venous Mode	While monitoring Hb levels, there are two blood sample sources from which Hb readings can be obtained: ***Arterial*** and ***Venous***. Arterial Hb measurements can be expected to be slightly lower than the Hb measurement derived from venous blood. This feature allows you to tailor the SpHb measurement to clinical practice and/or setting. Options: ***Arterial***, ***Venous***. Configure in ***Monitor Setup > Advanced > Default Setup > Measurement Settings***.
SpHb Averaging	This feature allows you to fine tune SpHb responsiveness to achieve the desired level of visibility to rapid variations in SpHb values. Options: ***Short*** (1 minute), ***Medium*** (3 minutes), ***Long*** (6 minutes) Configure in ***Monitor Setup > Advanced > Default Setup > Measurement Settings***.
SpHb Precision	Allows you to select preferred level of SpHb value granularity/precision: • Nearest 0.1 (default) • Nearest 0.5 • Whole number This feature allows you to easily track SpHb value fluctuations and to configure to clinical practice and/or setting. NOTE Ask service to setup a preferred level of precision.
SpHb Sensor Life	The reusable SpHb sensor is intended for spot-check SpHb measurements rather than continuous SpHb measurements (rainbow® single patient adhesive or resposable adhesive sensors are designed for continuous measurements). The reusable SpHb sensor includes a limited amount of time (or number of spot-check measurements). The purpose of the sensor life message is to tell the user how much time or how many spot-check measurements are still available on this SpHb sensor. The user is notified well in advance of sensor end of life so as to ensure they do not run out of measurements. NOTE With no time remaining, the sensor will allow SpHb monitoring until it has been off the patient for more than 5 minutes.
SpHb UOM (unit of measurement)	This feature allows you to adjust unit of measurement options for the SpHb values to be displayed with either g/dl or mmol/l, according to regional unit of measure. NOTE Ask service to change the unit of measurement if necessary.

Masimo rainbow® SET® feature	Description
SpMet	Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants.
SpO_2 Alarm Delay	Many desaturations are real, but transitory, and as such, may not require clinical intervention ("non-actionable alarms"). This option allows you to require that the SpO_2 value exceeds the alarm limit for a predetermined duration before an audible alarm, minimizing the risk that caregivers will be desensitized to audible alarms due to non-actionable events. The delay only affects audible alarms for SpO_2. It does not delay the on-screen *visual* indication of an SpO_2 alarm limit violation. This setting is automatically turned off if Rapid Desat Alarm Threshold is set active. Also, if nurse call is used, this setting will not delay remote alarm. Options (seconds): *0*, *5*, *10*, *15*. Configure in *Alarm Setup* or *Monitor Setup > Advanced > Default Setup > Measurement Settings*.
SpO_2 Averaging Time	This feature allows you to select the desired level of visibility to subtle variations in the measured value. Depending on the patient acuity and area of care, shorter averaging times are sometimes preferred (sleep testing) over longer averaging times (neonates) and vice versa. 8-second averaging is generally considered the most common averaging interval and recommended for most patients since it is short enough to provide visibility to subtle desaturations while also being long enough to minimize major changes in SpO_2 due to quick, transitory desaturations. Although averaging times greater than 10 seconds are more likely to reduce visibility to rapid, brief desaturations, this may be desirable in care areas where brief desaturations that do not require clinician intervention occur more often (for example, NICU). Options (seconds): *2-4*, *4-6*, *8*, *10*, *12*, *14*, *16*. Configure in *Monitor Setup > Advanced > Default Setup > Measurement Settings*.

Masimo rainbow® SET® feature	Description
SpO_2 Sensitivity Mode	Three sensitivity levels enable a clinician to tailor the response of the VC150 to the needs of the particular patient situation. *NORM* (Normal Sensitivity) *NORM* is the recommended sensitivity mode for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently. *APOD* (Adaptive Probe Off Detection Sensitivity) *APOD* is the recommended sensitivity mode where there is a high probability of the sensor becoming detached. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement. *Max.* (Maximum Sensitivity) *Max.* is recommended sensitivity mode for patients with low perfusion or when a low perfusion message displays in *APOD* or *NORM* mode. *Max.* mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings. When using the Maximum Sensitivity setting, performance of the Sensor Off detection may be compromised. If the VC150 uses *Max.* setting and the sensor becomes dislodged from the patient, the potential for false readings may realize due to environmental "noise" such as light, vibration, and excessive air movement. Configure default *Normal* or *APOD* in *Monitor Setup > Advanced > Default Setup > Measurement Settings*. Configure patient-specific *Max./Normal/APOD* in *Monitor Setup > SpO_2*.

Masimo rainbow SET® SpO_2 default settings

Masimo SpO_2 - Default Setup > Alarm Defaults	
SpO_2	Upper limit: OFF Lower limit: 90% Priority: Medium Latching/Non-latching: Latching
SpHb	Upper limit: 17 g/dL Lower limit: 7 g/dL Priority: Low Latching/Non-latching: Non-latching
RRa	Upper limit: 30 br/min Lower limit: 6 br/min Priority: Medium Latching/Non-latching: Non-latching
SpMet	Upper limit: 3% Lower limit: OFF Priority: Medium Latching/Non-latching: Non-latching
SpCO	Upper limit: 10% Lower limit: OFF Priority: Medium Latching/Non-latching: Non-latching
SpOC	Upper limit: 25% Lower limit: 10% Priority: Low Latching/Non-latching: Non-latching
PI	Upper limit: OFF Lower limit: OFF Priority: OFF Latching/Non-latching: Non-latching
Rapid desat alarm threshold	OFF
Desat Index 3D Alarm	OFF
Desat occurrences	2
Desat threshold	2%
Desat time period	1 hour
PI delta time period	None

PI delta range	50
Masimo SpO_2 - Default Setup > Measurement settings	
SpO_2 sensitivity mode	Normal
FastSat	Off
Perfusion index averaging	Short
SpO_2 Averaging Time	8 s
RRa averaging Time	~ 30 sec
RRa Pause Time	30 sec
RRa Freshness Timeout	5 min
SpHb mode	Arterial
SpHb Averaging	Medium
Smart tone	OFF
SpO_2 alarm delay	5 sec
RRa alarm delay	30 sec

Masimo rainbow SET® SpO_2 specifications

Measurement range	
Oxygen Saturation (SpO_2)	0 to 100%
Pulse rate (beat per minute or bpm)	25 to 240 bpm
Carboxyhemoglobin Saturation (SpCO)	0 to 99%
Methemoglobin Saturation (SpMet)	0 to 99.9%
Total Hemoglobin (SpHb)	0 to 25 g/dl
Respiratory Rate (RRa)	0 to 70 breaths per minute
Total Oxygen Concentration (SpOC)	0 - 35 ml/dl
Perfusion Index (PI)	0.02 to 20%

Data update	
Data update period	<2 seconds
Accuracy and motion tolerance (applies to adult/pediatric/infant/neonate unless otherwise indicated) **Refer to notes 1, 2, 3, 4, 5, 6, 7**	
Resolution	
SpO_2	1%
Pulse rate	1 bpm
SpCO	1%
SpMet	0.1%
SpHb - adult/pediatric/infant	0.1 g/dl
RRa	1 breath per minute
Saturation accuracy	
Without motion - adult/pediatric/infant	60 to 80% ± 3%
Without motion - adult/pediatric/infant	70 to 100% ± 2%, with neonates ± 3%
With motion	70 to 100% ± 3%
Low perfusion	70 to 100% ± 2%
SpCO - adult/pediatric/infant	1 - 40 ± 3%
SpMet	1 - 15 ± 1%
SpHb - adult/pediatric	8 - 17 ± 1 g/dl (arterial or venous)
RRa - adult/pediatric (> 10 kg)	4 - 70 ± 1 breath per minute
Pulse rate accuracy	
Without motion	25 to 240 bpm ± 3 bpm (rms)
With motion	25 to 240 bpm ± 5 bpm (rms)
Low perfusion	25 to 240 bpm ± 3 bpm (rms)

[1]SpO_2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO_2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet.

[2]The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range or 70-100% SpO_2 against a laboratory CO-oximeter and EGG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3]The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range or 70-100% SpO_2 against a laboratory CO-oximeter and EGG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[4]The Masimo SET® Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[5]The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bmp in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[6]SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

[7]The following substances may interfere with pulse CO-oximetry measurements:

- Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO_2 and SpCO measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Very low arterial oxygen saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements.
- Severe anemia may cause erroneous SpO_2 readings.
- Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of total bilirubin may lead to inaccurate SpO_2 SpMet and SpHb readings.

Note: Sensor Accuracy

Arms (root mean square of paired values; previously represented by ± 1 SD).

Sensor accuracy specified when used with Masimo SET® MX board using a Masimo patient cable for LNOP sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (rms error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ±Arms compared to the reference value. SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.

Masimo sensor accuracy specification

NOTE

For detailed information on patient population, sensor site and application refer to Masimo sensor instructions for use.

MASIMO PN	Part description	SpO_2 range 70% to 100%
2069	rainbow® DCIP-dc3 Pediatric Reusable Direct Connect Sensor, 3 ft. (SpO_2, SpCO, SpMet) 1/box,	± 2% without motion (with motion ± 3%)
2070	rainbow® DCIP-dc12 Pediatric Reusable Direct Connect Sensor, 12 ft. (SpO_2, SpCO, SpMet) 1/box,	± 2% without motion (with motion ± 3%)
2201	rainbow® DCI-dc3 Adult Reusable Direct Connect Sensor, 3 ft. (SpO_2, SpCO, SpMet) 1/box,	± 2% without motion (with motion ± 3%)
2202	rainbow® DCI-dc12 Adult Reusable Direct Connect Sensor, 12 ft. (SpO_2, SpCO, SpMet) 1/box,	± 2% without motion (with motion ± 3%)
2219	rainbow® R25-L Adult / Neonatal Adhesive Sensors (SpO_2, SpCO, SpMet) Single patient use 10/box, Use replacement tape 2623.	± 2% without motion (with motion ± 3%)
2220	rainbow® R20-L Infant Adhesive Sensors (SpO_2, SpCO, SpMet) Single patient use 10/box, Use replacement tape 2624.	± 2% without motion (with motion ± 3%)
2221	rainbow® R25 Adult Adhesive Sensors (SpO_2, SpCO, SpMet) Single patient use 10/box,	± 2% without motion (with motion ± 3%)
2222	rainbow® R20 Pediatric Adhesive Sensors (SpO_2, SpCO, SpMet) Single patient use 10/box,	± 2% without motion (with motion ± 3%)
2407	rainbow® DCI-dc8 Adult Reusable Direct Connect Sensor, 8 ft. (SpO_2, SpCO, SpMet) 1/box,	± 2% without motion (with motion ± 3%)
2414	rainbow® R1 25L Adult Adhesive Sensors (SpHb, SpO_2, SpMet) Single patient use 10/box, Use replacement tape 2623.	± 2% without motion (with motion ± 3%)
2415	rainbow® R1 20L Infant Adhesive Sensors (SpHb, SpO_2, SpMet) Single patient use 10/box, Use replacement tape 2624.	± 2% without motion (with motion ± 3%)
2501	M-LNCS™ DCI Adult Reusable Sensor, 3 ft. 1/box,	± 2% without motion (with motion ± 3%)

2502	M-LNCS™ DCIP Pediatric/Slender Digit Reusable Sensor, 3 ft. 1/box,	± 2% without motion (with motion ± 3%)
2508	M-LNCS™ Adtx Adult SpO_2 Adhesive Sensor, 18 in. Single Patient Use 20/box, Sterilizable.	± 2% without motion (with motion ± 3%)
2509	M-LNCS™ Adtx-3 Adult SpO_2 Adhesive Sensor, 3 ft. Single Patient Use 20/box, Sterilizable.	± 2% without motion (with motion ± 3%)
2511	M-LNCS™ Pdtx-3 Pediatric SpO_2 Adhesive Sensor, 3 ft. Single Patient Use 20/box, Sterilizable.	± 2% without motion (with motion ± 3%)
2505	M-LNCS™ YI Multisite Reusable Sensor, 3 ft. 1/box, Nonsterile Multiple Foam and Adhesive Wraps.	± 2% without motion (with motion ± 3%)
2507	M-LNCS® DBI Adult Soft Reusable Sensor, 3 ft. 1/box,	± 2% without motion (with motion N/A)
2512	M-LNCS™ Inf Infant SpO_2 Adhesive Sensor, 18 in. Single Patient Use 20/box, Sterilizable. Use replacement tape 2307.	± 2% without motion (with motion ± 3%)
2513	M-LNCS™ Inf-3 Infant SpO_2 Adhesive Sensor, 3 ft. Single Patient Use 20/box, Sterilizable. Use replacement tape 2307.	± 2% without motion (with motion ± 3%)
2514	M-LNCS™ Neo Neonatal/Adult SpO_2 Adhesive Sensor, 18 in. Single Patient Use 20/box, Sterilizable. Use replacement tape 2308.	± 2% without motion (with motion ± 3%)
2515	M-LNCS™ Neo-3 Neonatal/Adult SpO_2 Adhesive Sensor, 3 ft. Single Patient Use 20/box, Sterilizable. Use replacement tape 2308.	± 2% without motion (with motion ± 3%)
2516	M-LNCS™ NeoPt Neonatal SpO_2 Adhesive Sensor, 18 in. Single Patient Use 20/box, Sterilizable. Use replacement wrap 2309.	± 3% without motion (with motion ± 3%)
2517	M-LNCS™ NeoPt-3 Neonatal SpO_2 Adhesive Sensor, 3 ft. Single Patient Use 20/box, Sterilizable. Use replacement wrap 2309.	± 3% without motion (with motion ± 3%)
2518	M-LNCS™ NeoPt-500 Neonatal SpO_2 Non-Adhesive Sensor, 18 in. Single Patient Use 20/box, Sterilizable. Use replacement wrap 2322.	± 3% without motion (with motion ± 3%)
2519	M-LNCS™ Newborn Neonatal SpO_2 Sensor Single Patient Use 20/box, Sterilizable. Use replacement wrap 2309.	± 3% without motion (with motion ± 3%)
2520	M-LNCS™ Newborn Infant/Pediatric Infant/Pediatric SpO_2 Sensor Single Patient Use 20/box, Sterilizable. Use replacement wrap 2322.	± 2% without motion (with motion ± 3%)

2521	M-LNCS™ Trauma Adult SpO_2 Sensor Single Patient Use 20/box, Sterilizable. Use replacement wrap 2309.	± 2% without motion (with motion ± 3%)
2640	rainbow® DCIP-dc8 Pediatric Reusable Direct Connect Sensor, 8 ft. (SpO_2, SpCO, SpMet) 1/box, Nonsterile.	± 2% without motion (with motion ± 3%)
2696	rainbow® DCI Adult Reusable Sensor, 3 ft. (SpCO, SpMet, SpO_2) 1/box, Nonsterile.	± 2% without motion (with motion ± 3%)
2697	rainbow® DCIP Pediatric Reusable Sensor, 3 ft. (SpCO, SpMet, SpO_2) 1/box, Nonsterile.	± 2% without motion (with motion ± 3%)
2753	rainbow® ReSposable™ R2-25a Sensors Adult R2-25a disposable optical sensors (SpO_2, SpHb, SpMet) Single patient use 25-R2-25a /box (DOS) Nonsterile.	± 2% without motion
2755	rainbow® ReSposable™ R2-20a Sensors Pediatric/Slender Digit R2-20a disposable optical sensors (SpO_2, SpHb, SpMet) Single patient use 25-R2-20a /box (DOS) Nonsterile.	± 2% without motion
2815	Masimo Ambient Shield Accessory For use with rainbow Sensors. 10/pack.	N/A
3379	Optical Test Sensor 3ft. Direct Connect, used with Fluke simulator to validate rainbow parameter values.	N/A
3380	Optical Test Sensor 12ft. Direct Connect, used with Fluke simulator to validate rainbow parameter values.	N/A
3395	rainbow® ReSposable™ R2-25r Sensors Adult R2-25r reusable optical sensors (SpO_2, SpHb, SpMet). 20 patient uses 5-R2-25r /box (ROS) Nonsterile.	± 2% without motion
3411	rainbow® ReSposable™ R2-20r Sensors Pediatric/Slender Digit R2-20r reusable optical sensors (SpO_2, SpHb, SpMet). 20 patient uses 5-R2-20r /box (ROS) Nonsterile.	± 2% without motion
3418	rainbow® DCI SC 200 Adult reusable sensor, 3 ft. (SpHb, SpO_2 and SpMet). 200 Spot Checks or 33 hours continuous monitoring.	± 2% without motion (with motion ± 3%)
3419	rainbow® DCIP SC 200 Pediatric reusable sensor, 3 ft. (SpHb, SpO_2 and SpMet). 200 Spot Checks or 33 hours continuous monitoring.	± 2% without motion (with motion ± 3%)
3420	rainbow® DCI SC 400 Adult reusable sensor, 3 ft. (SpHb, SpO_2 and SpMet). 400 Spot Checks or 66 hours continuous monitoring.	± 2% without motion (with motion ± 3%)

3421	rainbow® DCIP SC 400 Pediatric reusable sensor, 3 ft. (SpHb, SpO_2 and SpMet). 400 Spot Checks or 66 hours continuous monitoring.	± 2% without motion (with motion ± 3%)
3456	Acoustic Respiration Sample Pack 1-RAS-125/1-RAS-125C Sensor.	4 to 70 ± 1 breath per minute
3457	rainbow® ReSposable™ R2-25 Sensor System Adult R2-25a disposable optical sensors & R2-25r reusable optical sensors (SpO_2, SpHb, SpMet). Single patient use 20-R2-25a / box (DOS) 1-R2-25r /box (ROS) Nonsterile.	± 2% without motion (with motion ± 3%)
3458	rainbow® ReSposable™ R2-20 Sensor System Pediatric R2-20a disposable optical sensors & R2-20r reusable sensors (SpO_2, SpHb, SpMet). Single patient use 20-R2-20a /box (DOS) 1-R2-20r /box (ROS) Nonsterile.	± 2% without motion (with motion ± 3%)
3647	rainbow® DCI SC-1000 Adult reusable sensor, 3 ft. (SpHb, SpO_2 and SpMet). 1000 spot-check uses of up to 10 minutes each or 168 hours of continuous monitoring).	± 2% without motion (with motion ± 3%)
3648	rainbow® DCIP SC-1000 Pediatric reusable sensor, 3 ft. (SpHb, SpO_2 and SpMet). 1000 spot-check uses of up to 10 minutes each or 168 hours of continuous monitoring).	± 2% without motion (with motion ± 3%)
1859	LNCS Adtx, Adult Adhesive Sensor, 18"	± 2% without motion (with motion ± 3%)
1860	LNCS Pdtx, Pediatric Adhesive Sensor, 18"	± 2% without motion (with motion ± 3%)
2328	LNCS Inf, Infant Adhesive Sensor, 18"	± 2% without motion (with motion ± 3%)
2329	LNCS Neo, Neonatal/Adult Adhesive Sensor, 18"	± 2% without motion (with motion ± 3%)
2330	LNCS NeoPt, Neonatal Preterm Adhesive Sensor, 18"	± 3% without motion (with motion ± 3%)
2317	LNCS Adtx-3, Adult Adhesive Sensor, 3 ft	± 2% without motion (with motion ± 3%)
2318	LNCS Pdtx-3, Pediatric Adhesive Sensor, 3 ft	± 2% without motion (with motion ± 3%)
2319	LNCS Inf-3, Infant Adhesive Sensor, 3 ft	± 2% without motion (with motion ± 3%)
2320	LNCS Neo-3, Neonatal/Adult Adhesive Sensor, 3 ft	± 2% without motion (with motion ± 3%)
2321	LNCS NeoPt-3, Neonatal Preterm Adhesive Sensor, 3 ft	± 3% without motion (with motion ± 3%)
2331	LNCS NeoPt-500	± 3% without motion (with motion ± 3%)
2411	LNCS Trauma Sensor	± 2% without motion (with motion ± 3%)
2412	LNCS Newborn Neonatal Sensor	± 3% without motion (with motion ± 3%)

2413	LNCS Newborn Infant/Pediatric Sensor	± 2% without motion (with motion ± 3%)
1863	LNCS DCI, Adult Reusable Sensor	± 2% without motion (with motion ± 3%)
1864	LNCS DCIP, Pediatric Reusable Sensor	± 2% without motion (with motion ± 3%)
2258	LNCS YI, Multisite Reusable Sensor	± 2% without motion (with motion ± 3%)
2653	LNCS DBI, Adult Reusable Soft Finger Sensor	± 2% without motion (with motion N/A)
1829	LNOP Adtx, Adult Adhesive Sensor, transparent tape	± 2% without motion (with motion ± 3%)
1025	LNOP Pdt, Pediatric Adhesive Sensors	± 2% without motion (with motion ± 3%)
1830	LNOP Pdtx, Pediatric Adhesive Sensor, transparent tape	± 2% without motion (with motion ± 3%)
1798	LNOP Neo-L, Neonatal Adhesive Sensors	± 2% without motion (with motion ± 3%)
1651	LNOP NeoPt-L, Neonatal Sensitive Skin Adhesive Sensors	± 3% without motion (with motivation ± 3%)
1800	LNOP Inf-L, Infant Adhesive Sensors	± 2% without motion (with motion ± 3%)
2203	LNOP Newborn Neonatal, Neonatal Sensors	± 3% without motion (with motivation ± 3%)
2204	LNOP Newborn Infant, Neonatal Sensors	± 2% without motion (with motion ± 3%)
1970	LNOP Blue, Neonatal/Infant/Pediatric Sensors	± 3.3% without motion
2358	LNOP Trauma Sensor	± 2% without motion (with motion ± 3%)
1269	LNOP DCI, Adult Reusable Sensor	± 2% without motion (with motion ± 3%)
1276	LNOP DCIP, Pediatric Reusable Sensor	± 2% without motion (with motion ± 3%)
1544	LNOP YI, Multisite Reusable Sensor	± 2% without motion (with motion ± 3%)
1560	LNOP DC-195 (LNOP Pv-150), 1/Box	± 2% without motion (with motion ± 3%)
3401	RAS-125c, Short Term Monitoring Acoustic Respiration Cloth Sensor. Adult Adhesive Sensors (RRa) Single patient use 10/ box, Nonsterile. Available in the US only.	4 to 70 ± 1 breath per minute
3403	Optical Test Sensor MLNCS Connector, used with Fluke simulator to validate rainbow parameter values.	N/A
2308	Replacement Tapes For LNCS®/M-LNCS™ Neo Series Sensors For use with LNCS/M-LNCS Neo/Neo-3 102/box,	sensor accessory; spare parts

2309	Replacement Wraps for LNCS®/M-LNCS™ NeoPt, NeoPt-3, Trauma and Newborn Neonatal Sensors For use with LNCS/ M-LNCS NeoPt/ NeoPt-3/ Trauma and Newborn Neonatal 10/pack,	sensor accessory; spare parts
2322	Replacement SofTouch Wraps for LNCS®/M-LNCS™ NeoPt-500, Newborn Infant / Pediatric For use with LNCS/M-LNCS NeoPt-500/Newborn Infant/Pediatric 10/pack,	sensor accessory; spare parts
2822	Replacement Tape for M-LNCS™ Blue. For use with M-LNCS Blue 50/pack, Nonsterile This product does not contain natural rubber latex.	sensor accessory; spare parts
2623	Replacement Tapes For rainbow® R1 25L and R25-L For use with rainbow R1 25L and R25-L 50/box, Nonsterile	sensor accessory; spare parts
2624	Replacement Tapes rainbow® R1 20L and R20-L For use with rainbow R1 20L and R20-L 50/box, Nonsterile	sensor accessory; spare parts
3475	RAS-125c, Acoustic Respiration Cloth Sensor Adult/Pediatric Adhesive Sensors (RRa) Single patient use 10/box, Nonsterile. Available in countries where cleared.	4 to 70 ± 1 breath per minute
3483	RAS-125c, Short Term Monitoring Acoustic Respiration Cloth Sensor Adult/Pediatric Adhesive Sensors (RRa) Single patient use 10/box, Nonsterile. Available in countries where cleared.	4 to 70 ± 1 breath per minute
2659	M-LNCS® Sensor Training Kit. Includes 1 LNCS Adtx, 1 LNCS Pdtx, 1 LNCS Inf, 1 LNCS Neo, 1 LNCS NeoPt sensor and 1 neonatal foot with application card, direction for use.	(adult, ped, inf, neo) ± 2% without motion (with motion ± 3%); (neoPt) ± 3% without motion (with motion ± 3%)
2654	M-LNCS™ to LNC Adapter Cable M-LNCS Series to LNC Patient Cable, 1.5 ft.	cable; no measuring function
3660	Dual Channel rainbow® Acoustic Monitoring Cable II for use with rainbow and M-LNCS SpO_2 sensor, and acoustic respiration sensors.	cable; no measuring function
3661	Dual Channel rainbow® Acoustic Monitoring Cable II for use with LNCS SpO_2, and acoustic respiration sensors.	cable; no measuring function
2404	rainbow® RC-12 rainbow 20-pin Patient Cable, 12 ft For use with rainbow and M-LNCS SpO_2 Only sensors.	cable; no measuring function
2405	rainbow® RC-1 rainbow 20-pin Patient Cable, 1 ft For use with rainbow and M-LNCS SpO_2 Only sensors.	cable; no measuring function
2406	rainbow® RC-4 rainbow 20-pin Patient Cable, 4 ft For use with rainbow and M-LNCS SpO_2 Only sensors.	cable; no measuring function

2055	Masimo cable red LNC-04	cable; no measuring function
2056	Masimo cable red LNC-10	cable; no measuring function
2057	Masimo cable red LNC-14	cable; no measuring function
2058	Masimo cable red PC-04	cable; no measuring function
2059	Masimo cable red PC-08	cable; no measuring function
2060	Masimo cable red PC-12	cable; no measuring function

Note: Sensor Accuracy Sensor accuracy specified when used with Masimo SET® MX Board using a Masimo patient cable for LNOP sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (rms error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ±Arms compared to the reference value. SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.	
Nominal Wavelengths	NOTE This information may be useful to clinicians, such as those performing photodynamic therapy.
Masimo's LNOP and LNCS sensors use Red and Infrared light emitting diodes. The wavelengths for all of the sensors except LNOP tip clip (LNOP TC-I), LNCS tip clip (LNCS TC-I), LNOP transflectance (LNOP TF-I), and LNCS transflectance (LNCS TF-I), are identified as follows:	
Wavelength	Infrared: 905 nm Red: 660 nm
The LNOP tip clip (LNOP TC-I) and LNCS tip clip (LNCS TC-I) sensors use different light emitting diodes. The wavelength information is as follows:	
Wavelength	Infrared: 880 nm Red: 653 nm
The LNOP transflectance (LNOP TF-I) forehead and LNCS transflectance (LNCS TF-I) forehead sensors use different light	
Wavelength	Infrared: 880 nm Red: 660 nm
The Masimo rainbow sensors use 7 or more different light emitting diodes. For SpO_2 calculations with a rainbow sensor, the wavelength values shown in the above tables are the same.	
Power dissipation	Infrared: 22.5 mW (max) Red: 27.5 mW (max)

Patent information

Masimo patents

For patent information, please visit www.masimo.com/patents.htm

Troubleshooting

This section discusses potential difficulties and suggestions for resolving them. If the difficulty persists, contact service or your local Innokas Medical representative.

Problem	Cause	Solution
The heart icon indicates a pulse, but no oxygen saturation or pulse rate values appear on the screen.	• Excessive patient motion may be making it impossible for the SpO_2 function to find a pulse pattern. • The sensor may be damaged. • The patient's perfusion may be too low to allow the SpO_2 function to measure saturation and pulse rate.	• Check the patient. • Check instructions provided by the sensor manufacturer for proper placement. • If possible, keep the patient still; check whether the SpO_2 sensor is applied securely and properly, and replace it if necessary; use the PI value to determine the strength of the signal and move the sensor to a new site; or use an adhesive sensor. • Replace the sensor.
Large sudden changes in the SpO_2 or the pulse rate values. Asterisks or signal quality unstable.	• Excessive patient motion may be making it difficult for the SpO_2 function to find a pulse pattern. • An electrosurgical unit (ESU) may be interfering with performance.	• Check the patient. • If possible, keep the patient still; check whether the sensor is applied securely and properly, and replace it if necessary; use the PI value to determine the strength of the signal and move the sensor to a new site. If an ESU is interfering: • Move the SpO_2 cable as far from the ESU as possible. • Plug the monitor and the ESU into different AC circuits. • Move the ESU ground pad as close to the surgical site as possible. • The sensor may need to be replaced with a new sensor.

Problem	Cause	Solution
The oxygen saturation measurement does not correlate with the value calculated from a blood gas determination.	• The SpO_2 calculation may not have correctly adjusted for the effects of pH; temperature; CO_2; or 2.3-DPG. • Accuracy can be affected by incorrect sensor application or use; intravascular dyes; bright light; excessive patient movement; venous pulsations; electrosurgical interference; and placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line. • The VC150 monitor calculates the displayed values whereas devices such as an anesthesia unit do the actual measurement and analysis.	• Check that calculations have been corrected appropriately for the relevant variable. In general, calculated saturation values are not as reliable as direct laboratory hemoximeter measurements. • If there is excessive light, cover the sensor with opaque material. • Circulation distal to the sensor site should be checked routinely. Refer to the sensor's directions for use supplied with the sensor for requirements on moving the sensor to another site to ensure adhesion, skin integrity, and correct optical alignment. If skin integrity changes, move the sensor to another site. • Try to keep the patient still, or change the sensor site to one with less motion. • Observe all instructions, warnings, and cautions in this manual and in the directions for use of the sensor. • If a device such as an anesthesia unit displays different values, use that information instead.
A valid SpO_2 signal was present but has disappeared.	• An NIBP determination on the same limb is in progress.	• Check the patient. • An alarm message code appears on the screen, and the audible alarm will sound immediately. • Move the sensor to the arm that is not connected to a blood pressure cuff.
An error message for sensor replacement appears.	• The sensor or cable may be the wrong type or defective, the cabling may be improperly connected.	• Check the patient. • If possible, keep the patient still; check whether the proper sensor/cable is applied securely and properly, and replace it if necessary. • Disconnect and reconnect the sensor.
An error message for sensor connection problem appears.	• The sensor is not completely connected. The interconnect cable or sensor wiring is faulty. • Ensure the appropriate sensor and cable are being used.	• Check the patient. • Check the sensor connection to the interconnect cable and the interconnect cable connection to the monitor. Then, if needed, replace the sensor or the interconnect cable. • Use only compatible sensors and cables.

Masimo low perfusion

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. This may occur even with a pulse rate that correlates with the ECG heart rate.

9 Nellcor SpO_2

Description

The SpO_2 parameter in the monitor is available in three different technologies:

- GE TruSignal
- Nellcor OxiMax™
- Masimo rainbow® SET®

The SpO_2 technology logo on the left side of the monitor, above the physical connector, will disclose which technology the monitor is equipped with. If you want to use a different SpO_2 technology than your monitor is currently equipped with, contact service to discuss the procedure. Use of Nellcor RR and Nellcor Saturation Pattern Detection requires licenses that can be purchased separately and may need specific accessories.

The SpO_2 function is calibrated to read functional arterial oxygen saturation. When a suitable SpO_2 sensor is connected to the monitor and to the patient, the measurement values will be shown on the screen. Pulse rate derived from SpO_2 appears in the ***PR (Pulse Rate)*** window and updates continuously. The primary source of pulse rate is always SpO_2, i.e., if SpO_2 is measuring when an NIBP determination is completed, the pulse rate derived from NIBP is not displayed. A tone sounds at a rate corresponding to the pulse rate and at a pitch corresponding to the SpO_2 saturation level. The pitch is highest at 100% oxygen saturation, and it continuously decreases as the saturation level falls.

CAUTION

The pulse rate derived from SpO_2 is a value calculated from oxygen levels. The pulse rate is not equal to the patient's actual heart rate.

Audible and visual alarms occur when SpO_2 levels are outside the alarm limits. and the monitor is in monitoring mode. When a parameter status alarm occurs, an alarm message appears at the top of the screen (rectangle in the image above).

SpO_2 safety

WARNINGS

Many factors may cause inaccurate readings and alarms, decreased perfusion, and/or low signal strength:

Interfering substances:

- Carboxyhemoglobin may erroneously increase SpO_2 readings.
- Methemoglobin (MetHb) usually represents less than 1% of the total Hgb, but in the case of methemoglobinemia that can be congenital or induced by some IV dyes, antibiotics (such as sulphas), inhaled gases, etc., this level increases sharply. Methemoglobin may cause inaccurate SpO_2 readings.
- Intravascular dyes (such as indocyanine green, methylene blue, etc.) at certain concentrations may cause inaccurate SpO_2 readings and/or decreased perfusion and corresponding signal strength, potentially causing inaccurate SpO_2 readings.
-Nail polish and artificial nails may cause inaccurate readings.

Physiological characteristics:

Some physiological characteristics may cause decreased perfusion and/or low signal strength and may potentially cause inaccurate SpO_2 readings:

- Cardiac arrest, hypotension, shock, severe vasoconstriction, severe anemia, hypothermia, venous pulsations, congestions, darkly pigmented skin, ventricular septal defects (VSDs)

Environmental conditions:

Some environmental conditions may cause interference or artifact and may potentially cause inaccurate SpO_2 readings.

- Excessive ambient light sources (e.g., infrared heat lamps, strobe lights, bilirubin lights, direct sunlight, operating room lights). To prevent such interference, cover the sensor with opaque material.
- Electrical interference/Electrosurgery
- Defibrillation - May cause inaccurate reading for a short amount of time.
- Excessive patient/sensor motion. Artifact can simulate an SpO_2 reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

Sensor placement:

- Sensor placement on the same extremity as a blood pressure cuff, arterial catheter or intravascular line; or arterial occlusion proximal to the sensor; or a sensor below the heart level may cause decreased perfusion and/or low signal strength and potentially cause inaccurate SpO_2 readings.
- Poor sensor fit may cause decreased or low signal strength and potentially cause inaccurate SpO_2 readings.
- Do not allow tape to block the sensor light emitter and detector as this may cause decreased perfusion and/or low signal strength and potentially cause inaccurate SpO_2 readings.
- Before using the Nellcor sensor, carefully read the Nellcor sensor instructions for use (document produced by Covidien).

WARNING

As with any wrap or clip-on sensor, pressure is exerted. Be cautious in using a wrap or clip-on sensor on patients with compromised circulation (e.g., peripheral vascular disease or vasoconstricting medications).

Allow sensor and cable to dry completely after cleaning. Moisture and dirt on the connector can affect the measurement accuracy.

Inaccurate SpO_2 data can result if a sensor is past its useful life. Therefore, re-evaluate the measurement periodically by performing additional assessment of the patient equipment, including consideration of use of alternate monitoring methods such as direct measurement of arterial oxyhemoglobin saturation (SaO_2).

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs, then check for conditions that may cause inaccurate SpO_2 readings. If the problem is still not resolved, check the SpO_2 module or sensor for proper functioning.

Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high.

If the perfusion index falls below 0.5%, the SpO2 values may be inaccurate.

A pulse oximeter or CO-oximeter should not be used as an apnea monitor.

A pulse oximeter should be considered an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition. Check that the pulse oximetry waveform is physiological in shape to ensure waveform quality and minimize noise spikes caused by motion conditions.

If you deactivate the ***SpO2 Sensor Off*** alarm, keep the patient under close surveillance.

Single-use products are not designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, and cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization and/or reuse.

Clean the surface of the probe before and after each patient use.

Do not loop the sensor cable into a tight coil or wrap around the device, as this can damage the sensor cable.

CAUTIONS

Do not sterilize reusable sensors by irradiation, steam, or ethylene oxide. See the sensor manufacturer's instructions for cleaning, sterilization, or disinfecting methods.

Do not place SpO_2 sensor on patient during magnetic resonance imaging (MRI). Adverse reactions include potential burns to patients as a result of contact with attachments heated by the MRI radio frequency pulse, potential degradation of the magnetic resonance image, and potential reduced accuracy of SpO_2 measurements. Always remove oximetry devices and attachments from the MRI environment before scanning a patient.

Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

Placing a sensor distal to an arterial line may interfere with adequate arterial pulsation and compromise the measurement of SpO_2.

The sensor disconnect error message and associated alarm indicate that the sensor is either disconnected or the wiring is faulty. The user should check the sensor connection and, if necessary, replace the sensor, interconnect cable, or both.

Placing a sensor on a polished or an artificial nail may affect accuracy.

Patient safety:

Do not place any clip-on sensor in a patient's mouth, on their nose or toes, on their thumb, or across a child's foot or hand.

Prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. Observe the sensor site frequently to assure adequate distal circulation. Sensor sites should be checked at least every 2 hours and rotated at least every 4 hours. Refer to instructions supplied with sensor.

If the sensor is not applied properly, the patient's skin could be injured or the ability of the monitor to measure oxygen saturation could be compromised. For example, a clip-on sensor should never be taped shut. Taping the sensor could damage the patient's skin or impair the venous return, thus causing venous pulsation and inaccurate measurement of oxygen saturation.

Excessive pressure from the sensor may cause necrosis of the skin.

The operating range for respiration rate is 4 to 40 breaths per minute. Use on patients with respiration rates outside this range may result in inaccurate displayed respiration rate values.

CAUTIONS

Monitor performance:

Place the sensor so that the LEDs and the photodiode are opposite each other.

Monitor performance:

When an SpO_2 sensor is located on the same limb as the NIBP cuff, SpO_2 readings will not be valid while the cuff is inflated. If valid SpO_2 readings are required during the entire blood pressure determination, attach the SpO_2 sensor to the limb opposite the one with the blood pressure cuff.

NOTES

- A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease pulse rate.
- SpO_2 and pulse rate values are filtered by an averaging technique, which determines how quickly the reported values respond to changes in the patient's saturation. Increased averaging time effects time to alarm for SpO_2 saturation and pulse rate limits.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- Software development, software validation, and risk and hazard analysis have been performed to a registered quality system.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter cannot distinguish between oxyhemoglobin and dyshemoglobins.
- Poor perfusion may affect the accuracy of measurement, especially when using an ear sensor.
- Check that the red light is lit in the sensor.
- Check that the waveforms (if enabled in monitor setup) and parameter values are displayed when the sensor is connected to the patient.

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate sensor measurements.

- Incorrect application of the recommended sensor
- Placement of the recommended sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Failure to cover the sensor site with opaque material in high ambient light conditions
- Excessive patient activity
- Dark skin pigment
- Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream
- Excessive patient talking
- Respiration rate outside the range of 4 to 40 breaths per minute
- Significantly irregular cardiac rhythms (three or more events of irregularity observed within 30 seconds)

Signal Loss

Loss-of-pulse signal can occur for several reasons.

- Recommended sensor applied too tightly
- Inflation of a blood pressure cuff on the same extremity as the attached sensor
- Arterial occlusion proximal to the recommended sensor
- Poor peripheral perfusion

Recommended Usage

Select an appropriate recommended sensor, apply it as directed, and observe all warnings and cautions presented in the Instructions for Use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the recommended sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with sensor performance. To prevent interference from ambient light, ensure the recommended sensor is properly applied and cover the sensor with opaque material.

If patient activity presents a problem, try one or more of the following remedies to correct the problem.

- Verify the sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that improves patient skin contact.
- Use a new sensor with fresh adhesive backing.
- Keep the patient quiet and still, if possible.

Patient Conditions

Application issues and certain patient conditions can affect the measurements of the monitoring system and cause the loss of the pulse signal.

- **Anemia** — Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The pulse oximeter may fail to provide an SpO_2 reading if hemoglobin levels fall below 5 gm/dl.
- **Dysfunctional hemoglobins** — Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulphemoglobin are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.
- **Additional possible patient conditions** may also influence measurements.
  - Poor peripheral perfusion
  - Excessive patient activity
  - Venous pulsations
  - Dark skin pigment
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring agents (nail polish, dye, pigmented cream)
  - Defibrillation
  - Excessive patient talking
  - Respiration rate outside the range of 4 to 40 breaths per minute
  - Significantly irregular cardiac rhythms (three or more events of irregularity observed within 30 seconds)

Related documents

- **Pulse Oximetry Sensor Instructions for Use** — Guides sensor selection and usage. Before attaching any of the various Covidien-approved Nellcor™ sensors to the monitoring system, refer to their **Instructions for Use**.
- **Saturation Accuracy Grid** — Provides sensor-specific guidance related to desired SpO_2 saturation accuracy measurements. Available online at www.covidien.com.

SpO_2 on the screen

When SpO_2 is not receiving measurement data, a double dash (--) appears in this window. When the sensor switches to operation mode, the SpO_2 parameter starts to receive data. If the data is valid, the derived SpO_2 value appears in this window and updates continuously. The values are displayed in %.

SpO_2 values are displayed on the lower right side of the monitor screen. The SpO_2 and PI values are displayed in cyan color by default. This can be changed in configuration mode. If the monitor is providing the temperature measurement the SpO_2 value will be located under the displayed temperature value.

The SpO_2 field consists of the SpO_2 label, the measured value in the middle and the measurement site underneath the parameter value. The measurement site choices are: ***Finger***, ***Nose***, ***Toe***, ***Earlobe***. The site name ***Other*** can be used to indicate it was none of the above. The default site is ***None***. Next to the measured value is a column of asterisks representing signal quality, as well as upper and lower limits for the SpO_2 value.

If the sensor is detached from the patient, the ***SpO_2*** status switches to 'off patient' and displays **--**.

NOTES

If pulse rate data from SpO_2 data is available, the ***Pulse Rate*** window is associated with this parameter and a heart symbol is displayed on screen. Refer to "Pulse rate" on page 10-1 for more information.

If accuracy for a SpO_2 derived parameter is not yet guaranteed, a dimmed value is displayed on screen.

Perfusion index measurement

The perfusion index (PI) measurement is a clinical tool that provides a dynamic numeric reflection of perfusion at the sensor site. PI is a relative value that varies from patient to patient. The perfusion index value appears in its own field under the label PI. The user can use the PI value to compare the strength of the pulse signal at different sites on a patient in order to locate the best site for the sensor, i.e., the site with the strongest pulse signal.

Signal Strength values are mathematically calculated perfusion values represented by asterisks. The SpO_2 signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of a Low Signal Quality message. The more asterisks there are the better the signal quality. The better the arterial blood flow is, the better signal quality is obtained. A strong pulse signal increases the validity of SpO_2 and pulse rate data.

Changing the SpO_2 alarm limits

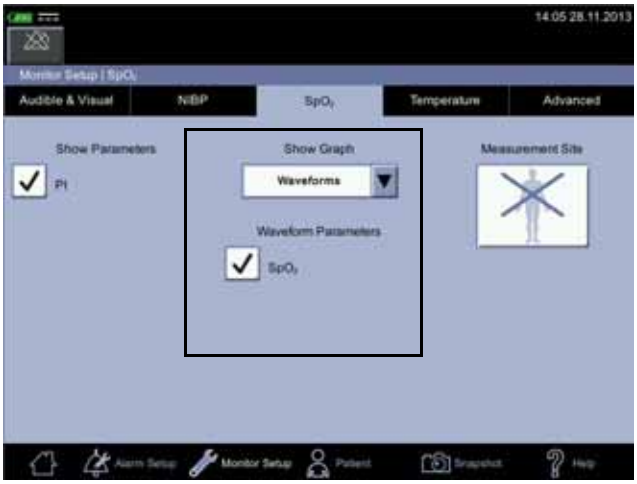
SpO_2 alarm limit adjustments can be set either A) by entering upper and lower limit values directly in a limit box on the home screen as instructed in "Using the numeric keypad" on page 3-12 or B) by adjusting limit values in the ***Alarm Setup*** screen as instructed in "Procedure for testing alarms" on page 3-11.

Pleth

The Plethysmographic waveform (Pleth) represents a real-time waveform for the relative SpO_2 pulsatile amplitude. The Pleth waveform is always automatically scaled to fit the window for the best display quality. The waveform uses the same color as the SpO_2 field.

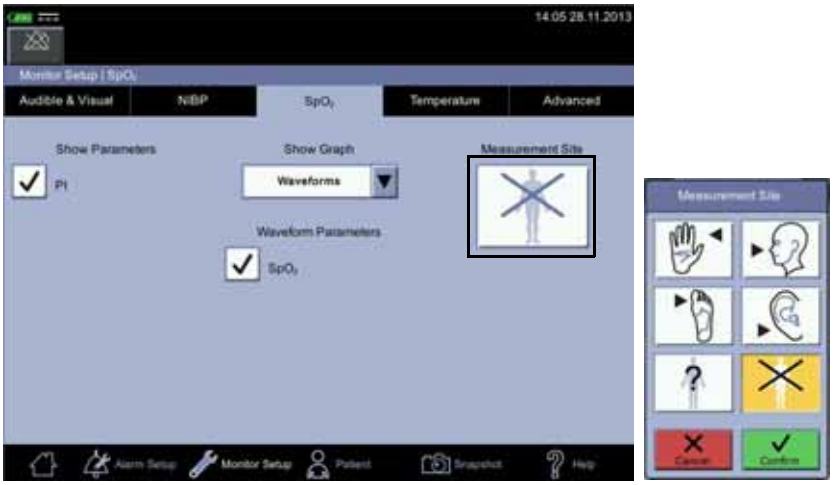
Pleth waveform settings

Select ***Waveforms*** in the drop-down menu under ***Show Graph*** in the ***Monitor Setup > SpO_2*** to display the ***Pleth***. Also select parameters to be displayed as waveforms (availability depends on which SpO_2 technology the monitor is equipped with and which options have been purchased).



SpO_2 measurement site

For documentation purposes, you can select the measurement site for SpO_2 in ***Monitor Setup > SpO_2*** before you start measuring SpO_2. A pop-up screen with the following images will appear: ***Finger***, ***Nose, Toe, Earlobe, Other*** or ***None***. It does not matter whether the site is on the left or right side of the patient. After the site is selected, it will be displayed on the home screen in the SpO_2 parameter window. The selection can be changed between the measurements. Admitting a new patient will reset the selection of the measurement site.



SpO_2 procedure

1. Check the label on the monitor to determine which SpO_2 technology the monitor is using. To assure optimal performance, use only accessories that are intended for that technology. If you cannot read the label, ask the nurse manager or service which SpO_2 technology is used.
2. Select a sensor that is appropriate for the patient, the clinical situation and for the SpO_2 technology used. Do not use an adult sensor on a neonatal/ pediatric patient and vice versa.

   WARNING
   Do not use a sensor, cables, or connectors that appear damaged or with exposed electrical contacts.

   Never repair a damaged sensor or cable; never use a sensor or cable repaired by others.

3. Ensure the VC150 is connected to power or the battery is fully charged.
4. Ensure the VC150 is powered on. The monitor has to display clinical mode and SpO_2 parameter on screen.
5. Connect an interface cable to the monitoring system sensor port.
6. Connect a correct sensor is connected to the interface cable and correctly applied to the patient as described in the Instructions for Use. The VC150 reports the appropriate sensor type in the message field when it detects the sensor. To obtain respiration rate, caregivers must use a Nellcor™ Respiratory Sensor and place it on the finger as described in sensor instructions. If Respiration Sensor is used: contact Innokas Medical service to upgrade the VC150 if the respiration rate parameter does not appear on the screen.
7. Select the measurement site in ***Monitor Setup > SpO_2***, if desired. A shortcut: Select SpO_2 parameter area on the home screen to jump to the ***SpO_2*** screen.
8. *Following the directions for use supplied with the sensor*, apply the sensor to the patient.
9. Proceed with monitoring. SpO_2 measurements run continuously and can run simultaneously with other measurements.
10. Clean the sensor as instructed in "Cleaning SpO2 sensors" on page B-8".

SpO_2 sounds

The monitor provides an audible tone for each pulse detected by the SpO_2 parameter. The pitch of the audible tone is directly related to the calculated saturation value. As the saturation value increases, the pitch rises. As the saturation value decreases, the pitch frequency goes down. This audible tone is silenced while an alarm sounds or the ***Day Volume*** or ***Night Volume*** is set to ***0***. Refer to "Audible & Visual" on page 3-19 in this section.

Alarms

If the SpO_2 parameter determines the signal to be valid, SpO_2 values are displayed. In case the signal quality deteriorates to a questionable level, the ***SpO_2*** or ***Pulse Rate*** values disappear from the screen and an alarm message for lost pulse signal is generated.

NOTE

The advanced signal processing of the Nellcor OxiMax™ algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The OxiMax™ algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which results in an increase in the dynamic averaging. The OxiMax™ algorithm continues to display SpO_2 and Pulse Rate values under such conditions. If the data update period exceeds 20 seconds, a ***Pulse search*** message is displayed in SpO_2 parameter window. If the data update period exceeds 30 seconds and the monitor alarms are enabled in monitoring mode, a low priority alarm is generated. If the data update period exceeds 40 seconds for SpO_2 or 50 seconds for Pulse Rate, the values disappear from the display, indicating a loss-of-pulse condition.

Alarm timer

The user can select between monitoring mode and spot-check mode. In spot-check mode, clinical alarms and related functions are not available. If an SpO_2 measurement continues for 5 minutes uninterrupted, the monitor automatically moves from spot-check mode to monitoring mode. The alarms will be enabled in monitoring mode.

If the probe is taken off and you want to measure the same patient without alarms, select spot-check mode again.

NOTE

To prevent misuse of the device, duration of the SpO_2 spot-check mode is limited to 5 minutes.

If SpO_2 is unable to be measured for some reason, then a technical status message that indicates the reason for not measuring will appear below the parameter value. If an abnormal technical status remains for ten seconds, then a low priority alarm is created.

An abnormal technical status will create an alarm in both spot-check and monitoring mode.

Compatible Nellcor accessories

All approved and VC150 compliant accessories are listed in the VC150 supplies and accessories document. Use only accessories listed in that document. If you already have an accessory that you want to use with the VC150 monitor, check whether it is listed in that document. If it not listed, do not use it with the VC150 monitor.

Nellcor SpO_2 and special features

Theoretical principles

The Nellcor SpO_2 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a Nellcor™ sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Ambient conditions, sensor application, and patient conditions can influence the ability of the monitoring system to accurately measure SpO_2. Pulse oximetry is based on two principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography).

A monitoring system determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector.

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation.

The monitoring system uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring system bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

This signal is processed by the pulse oximeter to determine patient SpO_2 and pulse rate data, which are displayed on the monitor user interface, system status, and alarm information. These data are stored on the monitor and available for subsequent export.

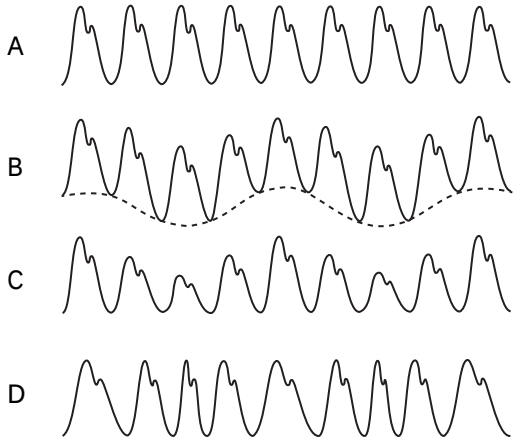
Nellcor Respiration Rate theory of operations

The Respiration Rate parameter, when used in conjunction with the VC150 and a Nellcor™ Respiratory Sensor, provides continuous non-invasive monitoring of arterial oxygen saturation, pulse rate and respiration rate using a single sensor. The Respiration Rate parameter provides an indication of central ventilatory drive by processing and interpreting the photoplethysmogram, or pleth.

The pleth signal is used to measure arterial oxygen saturation (SpO_2). A typical pleth pattern includes a regular cardiac 'pulse' waveform on top of a large constant baseline component, or DC component. Refer to A in figure below.

In clinical settings, both the cardiac pulse and baseline components may vary over time due to physiologic conditions and changes. In standard pulse oximetry, these variations are typically filtered out in order to accurately measure arterial oxygen saturation (SpO_2). These same subtle variations, however, may be used to derive respiration rate by tracking three types of changes associated with the respiratory cycle.

1. Baseline (DC) variation — Changes in intrathoracic pressure during the respiratory cycle influence venous return to the heart and result in baseline DC variation in the pleth. Refer to B in figure below.
2. Pulse amplitude variation — Changes in intrathoracic pressure during inspiration also lead to variation in cardiac stroke volume and result in pulse amplitude variations. Refer to C in figure below.
3. Respiratory sinus arrhythmia (RSA) — During the respiratory cycle, heart rate generally increases during inspiration and decreases during expiration. RSA results in pulse frequency variations. Refer to D in figure below.



Variations of the pleth due to respiration

The Respiration Rate parameter utilizes these subtle pleth variations to measure respiration rate. Note that the Respiration Rate parameter is an indicator of central ventilatory drive and is not a direct measure of ventilation.

Nellcor™ Sensor Technology

Use Nellcor™ sensors, which are specifically designed for use with the monitoring system. Identify Nellcor™ sensors by the Nellcor™ logo on the plug. All Nellcor™ sensors contain a memory chip carrying information about the sensor which the monitoring system needs for correct operation, including the sensor's calibration data, model type, troubleshooting codes, and error detection data.

This unique oximetry architecture enables several new features. When a Nellcor™ sensor is connected to the monitoring system, the monitoring system reads the information from the sensor memory chip, ensures it is error free, and then loads the sensor data prior to monitoring for new information. As the monitoring system reads sensor information, it sends the sensor model number to the monitoring screen. This process may take a few seconds. The sensor model number disappears after the monitoring system starts tracking the patient's SpO_2 and pulse rate.

Any monitoring system containing OxiMax technology uses calibration data contained in the sensor in calculating the patient's SpO_2. With sensor calibration, the accuracy of many sensors is improved, since the calibration coefficients can be tailored to each sensor.

Contact Covidien or a local Covidien representative for a Sensor Accuracy Grid listing all of the sensors used with the monitoring system. Covidien retains a soft copy at www.covidien.com.

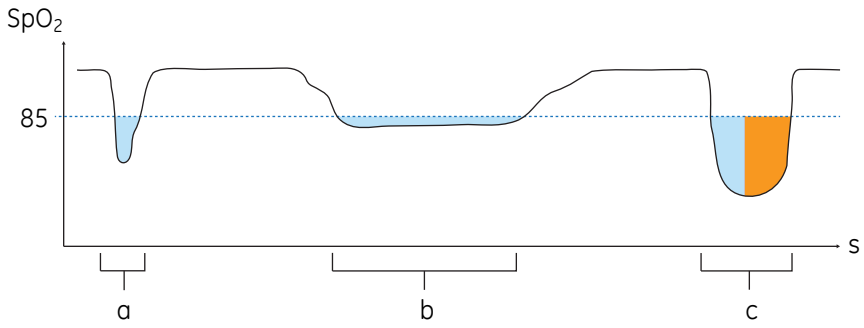
The monitoring system uses the information in the sensor, tailoring messages to better help the clinician troubleshoot client or data issues. The sensor automatically identifies its sensor type to the monitoring system when attached.

SatSeconds™ Alarm Management Parameter

The monitoring system monitors the percentage of hemoglobin binding sites saturated with oxygen in the blood. With traditional alarm management, upper and lower alarm limits are set to alarm at specific SpO_2 levels. When the SpO_2 level fluctuates near an alarm limit, the alarm sounds each time it violates the alarm threshold. SatSeconds monitors both degree and duration of desaturation as an index of desaturation severity. Thus, the SatSeconds parameter helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

Consider a series of events leading to a violation of the SatSeconds alarm limit.

An adult patient experiences several minor desaturations, then a clinically significant desaturation.



Series of SpO_2 Events

a. First SpO_2 Event

b. Second SpO_2 Event

c. Third SpO_2 Event

First SpO_2 Event

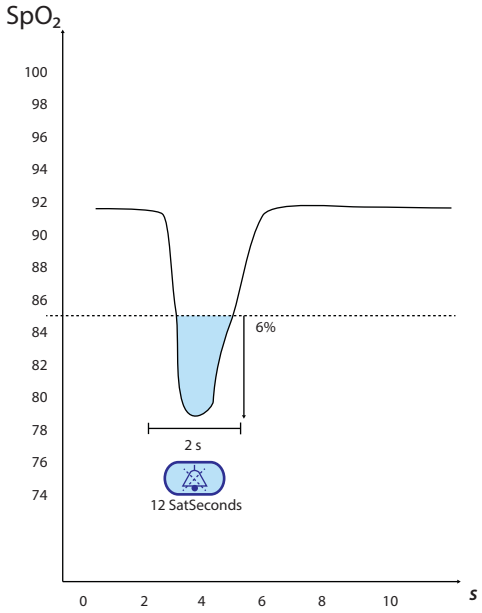
Consider the first event. Suppose the SatSeconds alarm limit is set to 25. The patient's SpO_2 drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%.

6% drop below the lower alarm limit threshold
× 2 second duration below the lower threshold

---

12 SatSeconds; no alarm

Because the SatSeconds alarm limit is set to 25 and the actual number of Sat-Seconds equals 12, there is no audible alarm.



First SpO_2 Event: No SatSeconds Alarm

Second SpO_2 Event

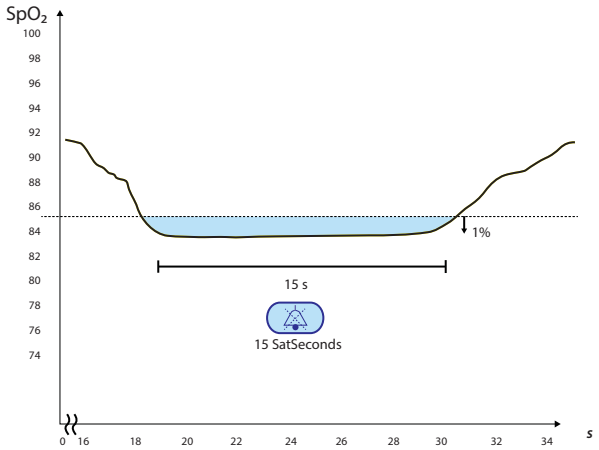
Consider the second event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO_2 drops to 84% and the duration of the event is 15 seconds before saturation again exceeds the lower alarm threshold of 85%.

1% drop below the lower alarm limit threshold
× 15 second duration below the lower threshold

---

15 SatSeconds; no alarm

Because the SatSeconds alarm limit is set to 25 and the actual number of SatSeconds equals 15, there is no audible alarm.



Second SpO_2 Event: No SatSeconds Alarm

Third SpO_2 Event

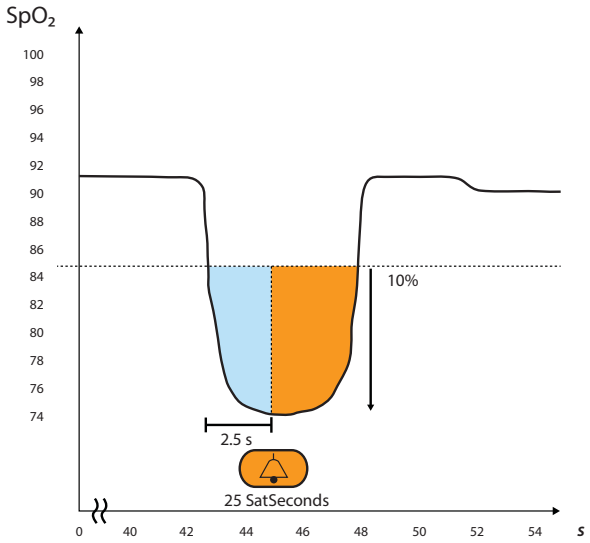
Consider the third event. Suppose the SatSeconds alarm limit is still set to 25. During this event, the patient's SpO_2 drops to 75%, which is 10% below the lower alarm threshold of 85%. Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds, an alarm sounds.

10% drop below the lower alarm limit threshold
× 2.5 second duration below the lower threshold

---

25 SatSeconds; results in an alarm

At this level of saturation, the event cannot exceed 2.5 seconds without invoking a SatSeconds alarm.



Third SpO_2 Event: Triggers SatSeconds Alarm

The SatSeconds Safety Net

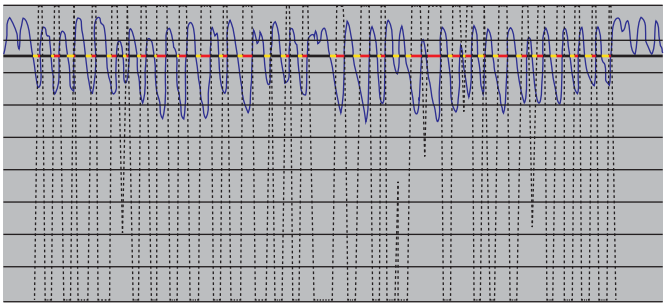
The SatSeconds "Safety Net" is for patients with saturation levels frequently falling below the limit, but not staying below the limit long enough for the Sat-Seconds time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm sounds even if the SatSeconds time setting has not been reached.

OxiMax SPD™ Alert Parameter

WARNING
Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.

CAUTION
Do not modify any other alarm settings while using the SPD™ parameter.

The OxiMax SPD™ Alert (SPD) method of detecting patterns of desaturation in adults is a function of the software within the monitoring system, which detects repetitive occurrences of desaturation followed by resaturation. These patterns are indicative of repetitive reductions in airflow through the upper airway and into the lungs. With the SPD parameter enabled, the default value for SatSeconds alarms is 100.



Clinically Significant Desaturation Patterns

The OxiMax SPD™ Alert (SPD) parameter detects patterns of desaturation in adults that are indicative of repetitive reductions in airflow through a patient's upper airway into the lungs. Relative reductions in a patient's minute ventilation over a period of time may cause a progressive drop in alveolar partial pressure of oxygen, leading to arterial desaturation. If these decreases in ventilation are repetitive, they generate distinct patterns in the saturation trend. Patterns of repetitive desaturation often develop gradually over time, increasing in severity.

Detection of patterns indicates that a patient might be suffering progressively severe decrements in airflow that may increase in acuity if left untreated.

Patterns of desaturation are multiple, sequential occurrences of a desaturation followed by a resaturation. The SPD™ parameter qualifies patterns of desaturation resulting from such repetitive reductions in airflow based on specific characteristics.

The SPD™ parameter qualifies these patterns of desaturation over a period of six (6) minutes. Depending on the sensitivity setting for SPD, patterns that persist may result in an SPD alarm, alerting the caregiver to the condition.

- The severity of the desaturation event (the depth of the desaturation during the event) and the extent of the following resaturation
- The regularity of the desaturation events (how often the pattern repeats)
- The slope of the desaturation/resaturation trends that form the events

The SPD™ parameter communicates information to the caregiver about these patterns of desaturation in a variety of ways with icons and alarms.

When the indicator reaches capacity, indicating the SPD™ limit has been reached, an audible alarm sounds and an alarm message flashes. The default setting of one (1) is the most sensitive to desaturation patterns and results in more frequent alarms. For less frequent alarms, use a less sensitive setting of two (2) or three (3).

NOTE

Unrecognized repetitive reductions in airflow through the upper airway occur in some clinically significant scenarios. Patients exhibiting sleep apnea symptoms were used in studies to validate the SPD™ Alert parameter. The presence of repetitive reductions in airflow was scored using a standard diagnostic polysomnogram. Study results indicate SPD is a sensitive marker in detecting repetitive reductions in airflow.

Pulse Rate Delay Alarm Management Parameter

The monitoring system also monitors pulse rate by determining the number of pleth waves over unit time. With traditional alarm management, upper and lower alarm limits are set for monitoring pulse rate. When pulse rates fluctuate near an alarm limit, alarms trigger with each violation. Pulse Rate Delay allows a period of threshold violation before the pulse rate alarm sounds. Thus, it distinguishes clinically significant events from minor and brief pulse rate limit violations that result in nuisance alarms.

To use Pulse Rate Delay, set the traditional alarm management upper and lower pulse rate alarm limits. Then, set Pulse Rate Delay. The Pulse Rate Delay limit controls the time the pulse rate level crosses either limit before an audible alarm sounds.

Required Pulse Oximetry Sensor Usage (for respiration rate)

To obtain respiration rate, caregivers must use a Nellcor™ Respiratory Sensor. If caregivers use alternate sensors, listed in the Operator's Manual, the monitor continues to post both SpO_2 and pulse rate data and dashes in the RR field. If caregivers use a respiratory sensor, the monitor will post both SpO_2 and pulse rate and respiration rate will be posted when enough data are available. The monitor will display dashes in the RR field for instances where it is unable calculate a respiration rate. If such is the case, examine all possible performance considerations.

Prerequisites

Before starting a monitoring session, confirm the following:

• The monitoring system is powered on, has successfully completed its power-on self-test, and has the respiration rate parameter enabled. Contact a qualified service technician to have the monitoring system upgraded if the respiration rate parameter does not appear on the screen.

• The monitoring system is connected to power or the battery is fully charged.

• An interface cable is connected to the monitoring system sensor port as described in the Operator’s Manual.

• A respiratory sensor is connected to the interface cable and correctly applied to the patient as described in the Instructions for Use. The monitoring system reports the appropriate sensor type in the message field when it detects the sensor.

Connection to Nellcor™ Sensors

WARNING

Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

The top of the monitoring system screen indicates the sensor type when connecting a recommended sensor to the monitoring system or when the monitoring system completes POST with an attached sensor.

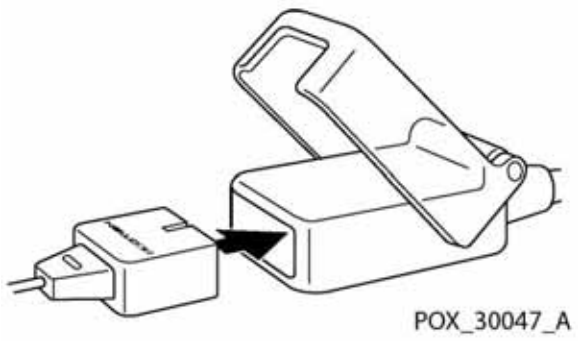
NOTES

Physiological conditions such as excessive patient movement, medical procedures, or external agents such as dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream may interfere with the monitoring system¡¦s ability to detect and display measurements.

Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001.

To fully connect a Nellcor sensor

1. Firmly connect a Nellcor interface cable to the monitoring system¡¦s sensor port. Reference "Rear view and left side" on page 2-2, to identify the port.
2. Open the plastic latch at the other end of the interface cable.



3. Plug the interface cable and recommended sensor together.
4. Snap the plastic latch down over the connectors.
5. When the monitoring system detects a valid pulse, it enters the monitoring mode and displays real-time patient data.
6. Apply the recommended sensor to the patient after reading the Instructions for Use accompanying the sensor.
7. Detach the recommended sensor from the patient on completion of monitoring.

WARNINGS

Nellcor-labeled monitors are only compatible with Nellcor™ sensors and accessories, which are available from your Innokas Medical representative or from Nellcor or its local representative. Other sensors or accessories may cause improper SpO_2 performance. Use only Nellcor™ sensors with ***purple***, ***white*** or ***navy blue*** plugs (connectors) and cables. Use of another pulse oximetry cable will have an adverse effect on performance. Do not attach any cable that is intended for computer use to the sensor port.

For monitors with Nellcor technology, use only Covidien (Nellcor)™ sensors and accessories. Incompatible components can result in degraded performance and/or device malfunction.

Intravascular dyes (such as indocyanine green, methylene blue, etc.) and darkly pigmented skin can adversely affect SpO_2 readings.

Significant amounts of dysfunctional hemoglobins (such as carboxyhemoglobin, methemoglobin, etc.) may adversely affect oximetry performance.

Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high.

Long cables (such as the sensor or extension cable) may cause patient strangulation if routed incorrectly.

Unless accessories and the monitor are used according to the operator's manual and in compliance with EMC standards, electromagnetic interference by defibrillators, MRIs or electro-surgical units may disturb the measurement process and cast doubt on its reliability.

Nellcor™ Respiration Rate parameter is intended for the continuous noninvasive monitoring of respiration rate in adult patients who are well perfused during non-motion conditions. Oximax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

RR is not a direct measure of ventilation; the clinician should always consider clinical signs and symptoms when assessing the patient.

Do not use RR with patients with significantly irregular cardiac rhythms.

Certain types of disturbances may degrade RR accuracy or result in no display.

The operating range for RR is 4 to 40 breaths per minutes. Use of RR on patients who are breathing outside this range may result in inaccurate RR values.

The RR software may give inaccurate readings due to aliasing conditions, when patient's BRPM exceeds 50% of pulse rate.

WARNINGS

Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.

Do not modify any other alarm settings while using the SPD™ parameter.

Use of the SPD™ parameter does not change the need to set threshold limits appropriate to the patient being monitored.

Should the caregiver acknowledge an SPD™ alarm, this resets the index that tracks repetitive patterns of desaturation.

External factors, including certain ambient conditions, sensor application errors, and certain patient conditions, may compromise the accuracy of the displayed respiration rate value. Always consider clinical signs and symptoms when assessing the patient and before intervening in response to a respiration rate alarm.

Respiration Rate is not intended for use as an apnea monitor. During apnea, Respiration Rate may post a non-zero number.

Respiration Rate should not be used on patients with significantly irregular cardiac rhythms (defined as three or more events of irregularity observed within 30 seconds) because the presence of these irregular cardiac rhythms may cause inaccurate respiration rate values or the loss of displayed respiration rate information. Safety and effectiveness of Respiration Rate in patients with significantly irregular cardiac rhythms have not been established. Use an alternate means of monitoring ventilatory status for patients with significant cardiac dysrhythmia.

Safety and effectiveness of respiration rate in patients on mechanical ventilation have not been established.

Safety and effectiveness of respiration rate in pediatric and neonatal patients have not been established.

Safety and effectiveness of respiration rate in pregnant or lactating women have not been established.

Use of the Respiration Rate parameter does not change the need to set threshold limits appropriate to the patient being monitored.

CAUTIONS

The respiration rate value is generated from SpO_2 to provide a reference for respiration rate. It is not the actual value for the respiration rate.

SPD™ (Saturation Pattern Detection) can be used only if SatSeconds is active. It cannot be used without SatSeconds.

Do not use NIBP or constricting instruments on the same appendage as the sensor.

Do not simultaneously be in contact with device connectors and the patient.

Do not immerse sensors.

Utilize hospital grade line cords in AC-powered systems.

Treat SPD™ alarm as lower priority than SatSeconds.

A low SpO_2 alarm limit of at least 90% is recommended when monitoring patients on supplemental oxygen.

Accuracy of Respiration Rate was established using bench-top testing and clinical studies in 26 healthy volunteers and 53 hospitalized patients. Hospital studies were conducted using convenience sampling and did not necessarily include all patient conditions found in hospitals and hospital-type settings. These clinical study results may not generalize to all patient conditions. Use caution in patient populations in which a displayed respiration rate value outside of the stated accuracy specification could present a serious risk or hazard.

An SpO_2 alarm may be the first indication of hypoventilation.

Respiration rate may present inaccurate respiration rate values when respiration rate exceeds 50% of heart rate. This situation, though rare, may occur under conditions including, but not limited to, any of the following: patients with high respiration rate and low heart rate, patients taking beta blockers, or patients with specific medical conditions such as sick sinus syndrome.

Respiration rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway. Always consider clinical signs and symptoms when assessing the patient and before intervening in response to a respiration rate alarm.

NOTE

Respiration Rate values are calculated every five seconds. Users should be aware that the reported respiration rate represents an average over a period of time and does not necessarily represent the instantaneous respiration rate. Low and high respiration rate alarms are triggered immediately when the reported rate falls outside the alarm limits and no further alarm delay is applied.

Nellcor SpO_2 default settings

Nellcor SpO_2 - Default Setup > Alarm Defaults	
SpO_2	Upper limit: OFF Lower limit: 90% Priority: Medium Latching/Non-latching: Latching
RR	Upper limit: 30 br/min Lower limit: 6 br/min Priority: Medium Latching/Non-latching: Non-latching
PI	Upper limit: OFF Lower limit: OFF Priority: OFF Latching/Non-latching: Non-latching
Response Mode	Normal
SPD Sensitivity	OFF
SatSeconds	OFF
Pulse Rate Alarm Delay	OFF

Nellcor SpO_2 configuration

Settings for specific Nellcor features can be selected in ***Alarm Setup*** (the monitor must be in monitoring mode). Refer to the table below for more information.

Nellcor feature	Description
Pulse Rate Alarm Delay management parameter	The oximeter monitors pulse rate by determining the number of pleth waves over unit time. With traditional alarm management, upper and lower alarm limits are set for monitoring pulse rate. When the pulse rate fluctuates near an alarm limit, the alarm sounds each time it violates an alarm limit. Use the ***Pulse Rate Delay*** feature to distinguish clinically significant events from minor and brief pulse rate limit violations that result in nuisance alarms. The ***Pulse Rate Delay*** feature allows a period of threshold violation before the pulse rate alarm sounds. Thus, the ***Pulse Rate Delay*** feature distinguishes clinically significant events from minor and brief pulse rate limit violations that may result in nuisance alarms. To use the ***Pulse Rate Delay*** feature, set the traditional alarm management upper and lower pulse rate alarm limits. Then, set the ***Pulse Rate Delay***. The ***Pulse Rate Delay*** limit controls the time the pulse rate level crosses either limit before an audible alarm sounds. Options: ***Off***, ***5***, ***10*** seconds
Response mode	The response mode establishes the frequency the oximeter uses to calculate, record, and display SpO_2 saturation levels, but does not affect the calculation of pulse rate. The response mode, however, may impact the SPD™ (saturation pattern detection) alarm. When in FAST response mode, the monitoring system may produce more SpO_2 and pulse rate alarms. ***Normal*** The default response mode responds to changes in blood oxygen saturation in 5 to 7 seconds when calculating % SpO_2. When in the normal mode, the screen does not display the fast mode icon. ***Fast*** Fast mode responds to changes in blood oxygen saturation levels in 2 to 4 seconds when calculating % SpO_2. This can be particularly helpful for situations that require close monitoring. The fast mode text in italics appears above the SpO_2 parameter value when in fast mode.

Nellcor feature	Description
SatSeconds alarm management parameter 	With traditional alarm management, upper and lower alarm limits are set for monitoring SpO_2. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an audible alarm immediately sounds. When the percent SpO_2 fluctuates near an alarm limit, the alarm sounds each time the limit is violated. To prevent these nuisance alarms, the ***SatSeconds*** alarm management feature controls the time that the percent SpO_2 level may fall outside the alarm limits before an audible alarm sounds. Choose either ***Off***, ***10***, ***25***, ***50***, or ***100*** seconds. ***SatSeconds*** is always 100 when SPD™ is active. The ***SatSeconds*** number is calculated by taking the amount the current saturation value is out of limits and multiplying it by the amount of time it has been out of those limits. For example, at a ***SatSeconds*** setting of 50, an alarm goes off if the patient is: • 5 points below the threshold × 10 seconds • 10 points below the threshold × 5 seconds The ***SatSeconds*** "safety net" is for patients with saturation levels frequently falling below the limit, but not staying below the limit long enough for the ***SatSeconds*** time setting to be reached. If the patient has had three or more SpO_2 threshold violations within a 60-second period, the alarm will sound whether or not the patient has exceeded the ***SatSeconds*** setting. For mild or brief SpO_2 limit violations, use the Sat-Seconds parameter to reduce nuisance alarms. With the SatSeconds parameter enabled, the monitoring screen includes a circle icon and its setting. The SatSeconds alarm limit value appears just below the circle icon. When the SatSeconds parameter is enabled, the circle icon fills in the clockwise direction as the alarm management system detects SpO_2 readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO_2 readings are within limits. When the icon fills completely, a medium-priority alarm sounds. The ***SatSeconds*** feature is indicated by a dashed circle icon with the current limit value below the icon. The icon fills clockwise in one-sixteenth increments by the ratio of current ***SatSeconds*** value to the current SpO_2 alarm limit.

Nellcor feature	Description
OxiMax SPD™ Alert Parameter 	Use the SPD™ alert (saturation pattern detection, SPD) parameter to detect patterns of desaturation in adults that are indicative of repetitive reductions in airflow through a patient's upper airway into the lungs. Patterns of desaturation are multiple, sequential occurrences of a desaturation followed by a resaturation. The SPD parameter qualifies patterns of desaturation resulting from such repetitive reductions in airflow based on specific characteristics. The SPD parameter qualifies these patterns of desaturation over a period of six (6) minutes. Depending on the sensitivity setting for SPD, patterns that persist may result in an SPD alarm, alerting the caregiver to the condition. • The severity of the desaturation event (the depth of the desaturation during the event) and the extent of the following resaturation • The regularity of the desaturation events (how often the pattern repeats) • The slope of the desaturation/resaturation trends that form the events The SPD™ alert uses a dashed triangle icon that is filled in one-third increments. When the triangle is filled up, it triggers an alarm to alert staff about these suspicious patterns. Using the SPD™ Alert parameter also triggers the SatSeconds parameter. With the SPD parameter enabled, the monitoring screen includes both triangle and circle icons and their settings. The SPD alarm sensitivity value appears just below the triangle icon. When the SPD parameter is enabled, the triangle icon fills from bottom to top as desaturation patterns develop. The triangle icon empties from top to bottom as patterns dissipate. When the icon fills completely, a low-priority alarm sounds. The monitoring system will sound the SPD alarm sooner if the SPD alarm sensitivity is set to the default value of one (1). A less sensitive setting will result in less frequent alarms. Options: ***Off, 1 - Most sensitive, 2 - Moderately, 3 - Least***

NOTE

Unrecognized repetitive reductions in airflow through the upper airway occur in some clinically significant scenarios. Patients exhibiting sleep apnea symptoms were used in studies to validate the SPD™ Alert parameter. The presence of repetitive reductions in airflow was scored using a standard diagnostic polysomnogram. Study results indicate SPD is a sensitive marker in detecting repetitive reductions in airflow.

Recommended actions for the use of Nellcor SpO_2

- Consult sensor directions for use for proper sensor application.
- Inspect extension cables and sensors periodically for damage and discontinue the use of these if damage is found.
- Implement a periodic testing strategy. Hand-held, battery-operated pulse simulation testers (SRC-MAX) are available from Covidien (Nellcor). Contact Nellcor's Technical Services Department at 1.800.635.5267 (U.S. only), or your local Nellcor representative.
- Review safety labeling based on the intended use of the equipment.

Nellcor SpO_2 specifications

NOTE

For detailed information on patient population, sensor site and application refer to Nellcor sensor instructions for use.

Measurement range		
SpO_2	1 to 100%	
Pulse rate	20 to 250 bpm	
Perfusion range	0.03 to 20%	
RR measurement range and accuracy	4 to 40 breaths/minute, ±1 breath/minute	
Data update		
Data update period	<2 seconds	
Averaging Time		
During normal measurement conditions in the Normal mode, the SpO_2 averaging time is six (6) to seven (7) seconds or approximately three (3) seconds in Fast mode.		
Oxygen Saturation Accuracy[1]		
Sensor Model Type	**LoSAT Range 60% to**	**Standard Range 70% to**
MAX-A, MAX-AL	± 3.0 digits	± 2.0 digits
MAX-N[2] (Adult and Neonatal)	± 3.0 digits	± 2.0 digits
MAX-P, MAX-I, Forehead SpO_2 Sensor	± 3.0 digits	± 2.0 digits
SpO_2 Non-adhesive, Adult, Neonatal, Preemie[3]	N/A	± 3.5 digits
MAX-R	N/A	± 2.0 digits
Low perfusion [4]	N/A	± 2.0 digits
The root mean square of the difference (rmsd) for set SpO_2 and displayed SpO_2 was 0.727. Seventy data points were taken in the test in the 70 to 100% saturation range. The root mean square of the difference (rmsd) for set PR and displayed PR was 1.581. Seventy data points were taken in the test in the 40 to 250 BPM pulse rate. All data for this test is stored at Nellcor/Covidien.		

Pulse Rate Accuracy	
Normal range	20 to 250 bpm ±3 bpm (rms)
Low perfusion**	20 to 250 bpm ±3 bpm (rms)

*Adult specifications are shown for OXIMAX MAX-A and MAX-N sensors with the N-600.
Saturation accuracy will vary by sensor type. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. Accuracy is based on deep hypoxia studies on healthy adult volunteer subjects. Arterial blood samples were analyzed simultaneously on multiple CO-oximeters.

**Applicability: OXIMAX MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

[1] Subjects used to validate SpO_2 measurement accuracies were healthy and recruited from the local population. Comprised of both men and women, subjects spanned a range of skin pigmentations and ranged in age from 18-50 years old. Accuracy specifications are based on controlled hypoxia studies with healthy non-smoking adult volunteers over the specified saturation SpO_2 range(s). Pulse oximeter SpO_2 readings were compared to SaO2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Pulse oximeter equipment measurements are statistically distributed; about two-thirds of pulse oximeter measurements can be expected to fall in this accuracy (Arms) range. Because scatter and bias of pulse oximeter SpO_2 and blood SaO_2 comparison commonly increase as the saturation decreases, and accuracy specifications are calculated from data spanning the stated range, different accuracy values may result when describing partially overlapping ranges.

[2] Clinical functionality of the MAX-N has been demonstrated on a population of hospitalized neonate patients. The observed SpO_2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85% to 99% SaO2.

[3] Clinical functionality has been demonstrated in a population of hospitalized neonate patients. The observed SpO_2 accuracy was 3.0% in a study of 57 patients with ages of 24 to 40 weeks, weight from 710 to 5,000 grams, and 185 observations made spanning a range of 63% to 99% SaO2.

[4] Specification applies to N-600x oximeter performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Arms (root mean square of paired values; previously represented by ± 1 SD).

Nellcor OxiMax sensor accuracy specifications

		SpO_2 Range	
Part description	Part number	LoSat 60% to 80%	70% to 100%
Max -A Adult Finger Adhesive Sensor - 24/box	MAXA (I)	± 3 digits	± 2 digits
Max -AL Adult Long Finger Adhesive Sensor - 24/box	MAXAL(I)	± 3 digits	± 2 digits
Max-P Pediatric Finger Adhesive Sensor - 24/box	MAXP (I)	± 3 digits	± 2 digits
Max-N Neonate Foot Adhesive Sensor - 24/box	MAXN(I)	± 3 digits	± 2 digits
Max-I Infant, Adhesive, Sensor - 24/box	MAXI(I)	± 3 digits	± 2 digits
Max-R, Adhesive, Nasal - 24/box	MAXR (I)		± 3.5 digits
OXIBAND (OXI-P/I) Pediatric/Infant Sensor	OXI-P/I		± 3 digits
OXIBAND (OXI-A/N) Adult/Neonate Sensor	OXI-A/N		± 3 digits
Nellcor Multisite Sensor D-YS Reusable	D-YS		± 3 digits
Nellcor DuraSensor DS-100A	DS100A (I)		± 3 digits
Forehead SpO_2 Sensor	MAXFAST(I)	± 3 digits	± 2 digits
Nellcor Adult Respiratory Sensor	10068119		± 2 digits
Preemie SpO_2 Sensor, Non-Adhesive (Box/24)	SC-PR (I)		± 2 digits
Neonatal SpO_2 Sensor, Non-Adhesive (Box/24)	SCNEO (I)		± 2 digits
Adult SpO_2 Sensor, Non-Adhesive (Box/24)	SC-A (I)		± 2 digits
Pediatric SpO_2 Sensor, Reusable (1/box)	D-YSPD		± 3.5 digits
Nellcor Ear-Clip D-YSE Sensor for D-YS	D-YSE		± 3.5 digits
Nellcor Tape ADH-A/N, use with OXI-A/N	ADH-A/N		N/A
Nellcor Tape ADH-P/I, use with Oxi-P/I Sensors	ADH-P/I		N/A
Cable Assy SpO_2 Nellcor OxiMax 3 m - Smart	2021406-001		N/A
Cable Assy SpO_2 Nellcor OxiMax 1.2 m - Smart	2021406-002		N/A

		SpO_2 Range
The MAX-N, D-YS, OXI-A/N, and OxiCliq N were tested on patients >40 kg.		
Neonatal sensor accuracy	When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ±1 digit, as compared to adult usage, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood. For example, MAX-N accuracy on neonates is ±3 digits, rather than ±2 digits.	
Sensor light source		
Wavelength	Infrared: 890 nm (nominal) Red: 660 nm (nominal)	NOTE This information may be useful to clinicians, such as those performing photodynamic therapy.
Power dissipation	Infrared: 22.5 mW (max) Red: 30 mW (max)	

Patent information

Nellcor patents

Covidien LP. US Patents: 5,485,847; 5,676,141; 5,743,263; 6,035,223;6,226,539; 6,411,833; 6,463,310; 6,591,123; 6,708,049; 7,016,715; 7,039,538; 7,120,479;7,120,480; 7,142,142; 7,162,288; 7,190,985;7,194,293; 7,209,774; 7,212,847; 7,400,919.

Troubleshooting

This section discusses potential difficulties and suggestions for resolving them. If the difficulty persists, contact service or your local Innokas Medical representative.

Problem	Cause	Solution
The heart icon indicates a pulse, but no oxygen saturation or pulse rate values appear on the screen.	• Excessive patient motion may be making it impossible for the SpO_2 function to find a pulse pattern. • The sensor may be damaged. • The patient's perfusion may be too low to allow the SpO_2 function to measure saturation and pulse rate.	• Check the patient. • Check instructions provided by the sensor manufacturer for proper placement. • If possible, keep the patient still; check whether the SpO_2 sensor is applied securely and properly, and replace it if necessary; use the PI value to determine the strength of the signal and move the sensor to a new site; or use an adhesive sensor. • Replace the sensor.

Problem	Cause	Solution
Large sudden changes in the SpO_2 or the pulse rate values. Asterisks or signal quality unstable.	• Excessive patient motion may be making it difficult for the SpO_2 function to find a pulse pattern. • An electrosurgical unit (ESU) may be interfering with performance.	• Check the patient. • If possible, keep the patient still; check whether the sensor is applied securely and properly, and replace it if necessary; use the PI value to determine the strength of the signal and move the sensor to a new site. If an ESU is interfering: • Move the SpO_2 cable as far from the ESU as possible. • Plug the monitor and the ESU into different AC circuits. • Move the ESU ground pad as close to the surgical site as possible. • The sensor may need to be replaced with a new sensor.
The oxygen saturation measurement does not correlate with the value calculated from a blood gas determination.	• The SpO_2 calculation may not have correctly adjusted for the effects of pH; temperature; CO_2; or 2.3-DPG. • Accuracy can be affected by incorrect sensor application or use; intravascular dyes; bright light; excessive patient movement; venous pulsations; electrosurgical interference; and placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line. • The VC150 monitor calculates the displayed values whereas devices such as an anesthesia unit do the actual measurement and analysis.	• Check that calculations have been corrected appropriately for the relevant variable. In general, calculated saturation values are not as reliable as direct laboratory hemoximeter measurements. • If there is excessive light, cover the sensor with opaque material. • Circulation distal to the sensor site should be checked routinely. Refer to the sensor's directions for use supplied with the sensor for requirements on moving the sensor to another site to ensure adhesion, skin integrity, and correct optical alignment. If skin integrity changes, move the sensor to another site. • Try to keep the patient still, or change the sensor site to one with less motion. • Observe all instructions, warnings, and cautions in this manual and in the directions for use of the sensor. • If a device such as an anesthesia unit displays different values, use that information instead.
A valid SpO_2 signal was present but has disappeared.	• An NIBP determination on the same limb is in progress.	• Check the patient. • An alarm message code appears on the screen, and the audible alarm will sound immediately. • Move the sensor to the arm that is not connected to a blood pressure cuff.
An error message for sensor replacement appears.	• The sensor or cable may be the wrong type or defective, the cabling may be improperly connected.	• Check the patient. • If possible, keep the patient still; check whether the proper sensor/cable is applied securely and properly, and replace it if necessary. • Disconnect and reconnect the sensor.

Problem	Cause	Solution
An error message for sensor connection problem appears.	• The sensor is not completely connected. The interconnect cable or sensor wiring is faulty. • Ensure the appropriate sensor and cable are being used.	• Check the patient. • Check the sensor connection to the interconnect cable and the interconnect cable connection to the monitor. Then, if needed, replace the sensor or the interconnect cable. • Use only compatible sensors and cables.

10 Pulse rate

Description

The ***PR*** (pulse rate) measurement displays heartbeats per minute (bpm), the source of the heartbeat data, a blinking heart icon and upper and lower alarm limits for the parameter. A beep provides an audible representation of the heartbeat. Also, the heart icon and the beep follow suit with the actual rhythm of the heart. The faster the heartbeat, the faster the icon blinks and the beep sounds, and vice versa.

The ***PR*** parameter receives data and waveform either from the NIBP parameter or the SpO_2 parameter (Masimo SET®, Nellcor or GE TruSignal). The SpO_2 parameter is always the primary data source for ***PR*** (displayed in yellow) whereas NIBP is the secondary (the ***PR*** displayed in the same color as the NIBP). If pulse rate data cannot be obtained from SpO_2, two dashes '**- -** ' are displayed in the ***PR*** window. If there is a recent enough NIBP for ***PR***, it is displayed. The data source is also displayed in technical area underneath the parameter value. Refer to the individual SpO_2 and NIBP chapters for more details on NIBP and SpO_2.

When the NIBP measurement is complete, a value is displayed in the ***PR*** window. The value is displayed as long as the results of that determination are displayed or until SpO_2 switches to monitoring mode.

NOTES

If Masimo rainbow SET® is the data source, the pulse rate values are filtered by an averaging technique that determines how quickly the reported values respond to changes in the patient's saturation. Increased averaging time affects time to alarm for SpO_2 saturation and pulse rate limits.

When NIBP is in STAT mode and is the source of pulse rate, the pulse rate value is not checked against its limits upon completion of the measurement.

Due to the algorithms the various sources use to measure the heartbeat, values in the ***PR*** window may differ when the monitor changes from one source to another.

A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease heart rate.

If an SpO_2-derived pulse rate is erratic, the pulse oximeter parameter may be unable to measure the pulse. If the pulse beep tone does not sound with each pulse, the pulse beep volume is turned off, or the speaker is malfunctioning.

Pulse rate alarm limits

Refer to "Alarm limit setup" on page 3-14 to set up ***Upper*** and ***Lower*** alarm limits for ***Pulse Rate***. The range for all sources is the same: ***Upper*** is ***35*** to ***235*** bpm and ***Lower*** is ***30*** to ***230*** bpm. The limits can be set in increments of 5 bpm.

When NIBP is the source for STAT mode measurement, the pulse rate value is not checked against the limits.

Pulse rate sound and settings

The monitor uses a light detector on the front panel to choose daytime or nighttime settings for pulse beep volume. Sound levels for beeps can be adjusted in the ***Monitor Setup > Audible & Visual*** screen anywhere between 0 and 100 (100 being the loudest). If you set the volume to zero, no tone will sound.

If SpO_2 is the source, there is one sound associated with this parameter: a beat detected sound. A pulse rate tone is indicated by an audible beep each time a beat is detected by the SpO_2 parameter.

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11 Welch Allyn temperature

Description

You can measure oral, axillary or rectal temperatures with the Welch Allyn SureTemp® Plus temperature parameter option. This parameter draws data from an electronic thermometer with a temperature-sensing device known as a thermistor at the tip of the probe. When the tip of the probe is brought in contact with surrounding tissue, the electrical resistance is measured, the algorithm calculates and displays the patient's temperature. The probe requires a probe cover and should never be used without one.

The temperature is displayed on the upper right corner of the monitor display. The temperature area displays the temperature in degrees Celsius (° C) or Fahrenheit (° F), time elapsed since last measurement and measurement site. The Welch Allyn SureTemp® Plus can operate in 2 different modes: predictive and monitor.

NOTES

A monitor with the Welch Allyn temperature technology configuration setting cannot perform Exergen temperature measurements and vice versa.

The thermometer case, connectors, and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all operating functions for proper operation.

The Welch Allyn SureTemp® Plus thermometer consists of high quality precision parts. Protect it from severe impact and shock. If the thermometer has been dropped or if you notice any signs of damage to the probe or instrument, do not use the thermometer. Contact service personnel to ensure proper operation prior to further use.

Safety

WARNINGS

To ensure patient safety and accurate Welch Allyn temperature measurement, use only Welch Allyn accessories and supplies.

Do not take a patient's temperature without using a Welch Allyn disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, and erroneous temperature readings. Use only Welch Allyn temperature probe covers.

Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

Do not reuse, or sterilize and reuse protective covers. Apply a new cover before each use.

WARNINGS

Visually inspect the probe covers for contaminants or damage prior to use.

Oral/axillary probes (blue ejection button at the top of the probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the incorrect removable probe well could result in patient cross-contamination.

Keep accessories out of patient's reach when not in use.

Do not leave the patient unsupervised during use of the probe and probe covers.

Always dispose of probe covers properly to prevent potential injury due to choking or slip-and-fall hazards. Ensure that probe covers are disposed of according to facility requirements or local regulations.

CAUTIONS

Be careful not to overextend the coiled cord of the temperature probe. Overextension can damage the probe coil connector interfaces.

Keep the temperature probe secured in the probe well when not in use.

Biting the probe tip while taking a temperature may result in damage to the probe.

Do not use any Welch Allyn probe or probe cover to select items on the touch screen: 1) The tip is sensitive and misusing it may damage the probe. 2) Using the probe or the probe cover as selection tool may scratch or damage the screen. 3) Using a used probe cover may increase the risk of cross-contamination via the touch screen.

The SureTemp Plus feature operates only when the probe well is correctly installed.

NOTE

Cross-contamination or nosocomial infection risk. Thorough handwashing before and after the measurement greatly reduces the risk of cross-contamination and nosocomial infection.

Measurement method

Predictive temperature measurement

When a new temperature measurement is initiated, the previous temperature measurement, if still displayed, will be cleared. When the probe is removed from the probe well, the temperature measurement starts with a predictive mode that measures the rate of change in temperature of the probe (with the probe cover) upon coming into contact with the patient's tissues. SureTemp® Plus temperature calculates a final temperature by extrapolating a terminal temperature from the measured warming rate without the need to wait for the probe tip to warm up to the patient's tissue temperature. The final temperature is stored in patient data.

The predictive temperature measurement ends when one of the following occurs:

- A final value is determined.
- The probe is inserted into the probe well.

If predictive measurement is not successful, the monitor will display the ***Temp No Determination*** alarm message. Select the snail icon to start monitor mode and to display real-time measurement data.

NOTE

The monitor will sound two beeps when a snapshot is automatically created after a measurement is completed and display the temperature value for a period defined in ***Monitor Setup > Advanced > Default Setup > General/ Measurement Expiration Time***.

Temperature measurement in monitoring mode

When the predictive measurement is complete, a snail icon appears next to the temperature figure on the monitor. Select the snail icon to switch to monitor mode, which measures the temperature continuously and displays it on the monitor screen. When the monitor mode is selected, the snail icon will be animated during the measurement.

It is recommended to hold the probe in place for at least 3 minutes (for oral and rectal) or 5 minutes (for axillary) to ensure that the probe tip has warmed up to the temperature of the surrounding tissues, giving a valid reading. The tip of the temperature probe continuously measures the temperature, but does not store it automatically. When the probe is properly positioned, and the temperature has stabilized, select ***Snapshot*** to create a snapshot with the monitor temperature measurement.

A monitor temperature measurement ends when the probe is inserted into the probe well. Monitor mode is not intended for long-term monitoring of patient's temperature; rather it is intended to produce a spot-check of the patient's temperature in cases where the predictive algorithm is unable to produce a result.

NOTE

Long-term continuous monitoring is not recommended in any mode. The monitor mode is automatically terminated after 10 minutes of monitoring.

Temperature probes

The temperature probes are color-coded to indicate which probes are used for oral/axillary or rectal measurement sites.

Color-coded temperature probes	
Color of the probe ejection button	**Measurement site**
Blue	Oral or axillary
Red	Rectal

Refer to the VC150 supplies and accessories document for temperature probe and probe cover reorder part numbers.

Proper storage of thermometer probe covers

To reduce the risk of contamination, keep the thermometer probe covers in their original 25-count box and store the box in the storage well provided on the monitor.

Welch Allyn temperature measurement

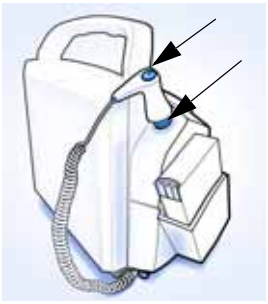
NOTES

Do not allow the tip of the temperature probe to come into contact with a heat source (e.g., hands or fingers) prior to taking a temperature measurement. If this occurs, allow 5 seconds for the probe tip to cool before proceeding.

Never insert a probe cover into the probe well.

Oral temperature measurement

1. Ensure that the patient has not done any of the following within 20 minutes prior to taking a temperature, as these may result in inability to take an accurate temperature:
   - Ingesting hot or cold liquids
   - Brushing teeth
   - Eating
   - Chewing gum or mints
   - Smoking
   - Activity such as climbing stairs or running



2. Check that a blue probe well and a probe with a blue ejection button are connected to the device. If not, obtain a blue probe well and a probe with the blue ejection button and connect these to the device as instructed in "Setting up temperature connection" on page 3-4. If these are already connected, ensure that the probe is in the probe well.
3. Always place a new transparent protective temperature probe cover on the probe before every oral measurement:
   - Remove the probe from the probe well.
   - Insert the probe shaft into a probe cover and firmly press down until retaining rings of the probe cover seat securely over the retaining ring barb of the probe shaft.
4. Verify that the probe cover fits snugly.

NOTE

Failure to firmly install the probe cover may result in the probe cover becoming loose or disengaged during use. Unintended probe cover ejection can lead to patient injury.

CAUTIONS

Injury may occur as a result of patient movement during the procedure.

Do not insert the probe cover into the probe well.

5. Select the temperature parameter to activate a shortcut to the ***Monitor Setup > Temperature*** screen.
6. Select ***Measurement Site***. Check that the temperature area displays ***Oral***. If this is not displayed, reselect the measurement site.
7. Have the patient open his/her mouth and carefully insert the probe tip deep under the tongue in the right or left sublingual pocket. Temperatures in other locations in the mouth can vary by more than 1° C or 2° F. Do not hand the probe to the patient to place in his or her own mouth. Have the patient close his or her lips over the probe.

Oral

Adult axillary

Pediatric axillary

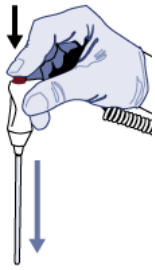
NOTES

Do not insert the probe cover into the probe well.

Do not allow the probe tip to come into contact with the patient until the probe is placed in the measurement site. Before this, any contact between the probe tip and the tissue or other material may cause inaccurate readings.

8. Always hold the probe in place, maintaining tissue contact until temperature is complete. Do not allow the patient to reposition the probe.

9. When the predictive measurement is complete, the result is captured to patient data automatically. If you question a reading, select the snail icon to switch to monitor mode.
10. When the monitor mode temperature measurement has stabilized, select ***Snapshot*** to create a snapshot and remove the probe from the patient.



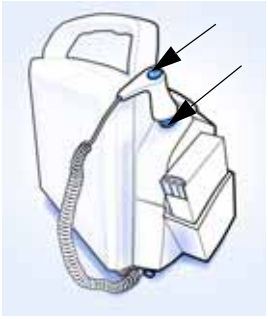
11. Eject the disposable probe cover by firmly pressing the ejection button on the top of the probe.

CAUTION

To prevent cross-contamination, properly dispose of the probe cover when the measurement is complete.

12. Place the probe in the probe well. Once you place the probe in the probe well, the temperature values will be cleared in 1 to 30 minutes, depending on the measurement expiration time setting.

Axillary temperature measurement



1. Adjust clothing to access the entire axilla. Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.
2. Check that a blue probe well and a probe with a blue ejection button are connected to the device. If not, obtain a blue probe well and a probe with the blue ejection button and connect these to the device as instructed in "Setting up temperature connection" on page 3-4. If these are already connected, ensure that the probe is in the probe well.
3. Always place a new transparent protective temperature probe cover on the probe before every axillary measurement:
   - Remove the probe from the probe well.
   - Insert the probe shaft into a probe cover and firmly press down until retaining rings of the probe cover seat securely over the retaining ring barb of the probe shaft.

4. Verify that the probe cover fits snugly.

NOTES

Failure to firmly install the probe cover may result in the probe cover becoming loose or disengaged during use. Unintended probe cover ejection can lead to patient injury.

Do not allow the probe tip to come into contact with the patient until the probe is placed in the measurement site. Before this, any contact between the probe tip and the tissue or other material may cause inaccurate readings.

CAUTIONS

Injury may occur as a result of patient movement during the procedure.

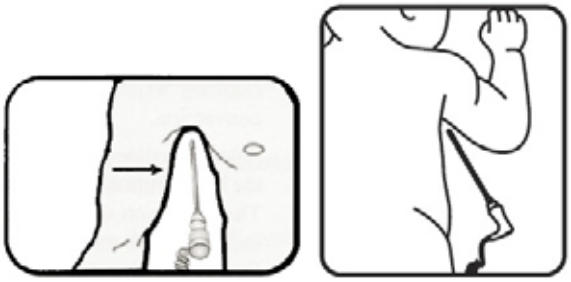
Do not insert the probe cover into the probe well.

5. Select the temperature parameter to activate a shortcut to the ***Monitor Setup > Temperature*** screen.
6. Select the adult or pediatric axillary icon on the ***Measurement Site*** screen.
7. Avoid folds in the axilla and place the probe tip as high as possible in the mid-axilla. Left image below is for adults, right image for infants and children.

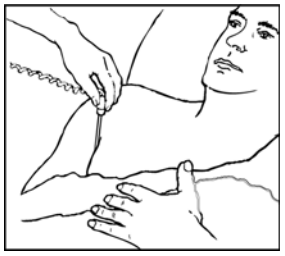
Oral

Adult axillary

Pediatric axillary

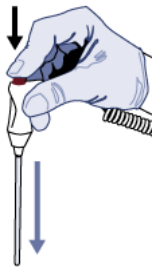


8. Insert the probe in the patient's axilla, making sure the tip of the probe is in contact with the skin and positioned as close as possible to the axillary artery.
9. Move the patient's arm close to the body to seal off the probe in the armpit. Keep the arm from moving during the measurement cycle.



10. Always hold the probe in place, maintaining tissue contact until temperature is complete. Do not allow the patient to reposition the probe.

11. When the predictive measurement is complete, the result is captured to patient data automatically. If you question a reading, select the snail icon to switch to monitor mode.
12. When the monitor mode temperature measurement has stabilized, select ***Snapshot*** to create a snapshot and remove the probe from the patient.

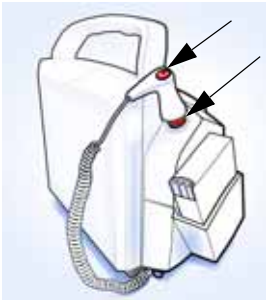


13. Eject the disposable probe cover by firmly pressing the ejection button on the top of the probe.

    CAUTION
    To prevent cross-contamination, properly dispose of the probe cover when the measurement is complete.

14. Place the probe in the probe well. Once you place the probe in the probe well, the temperature values will be cleared in 1 to 30 minutes, depending on the measurement expiration time setting.

Rectal temperature measurement



Use gloves or other measures to reduce the risk of cross-contamination as appropriate for good clinical practice and/or your institution's infection control policies.

1. Check that a red probe well and a probe with red ejection button are connected to the device. If not, obtain a red probe well and a probe with the red ejection button and connect these to the device as instructed in "Setting up temperature connection" on page 3-4. If these are already connected, ensure that the probe is in the probe well.
2. Always place a new transparent protective temperature probe cover on the probe before every rectal use:
   - Remove the probe from the probe well.
   - Insert the probe shaft into a probe cover and firmly press down until retaining rings of the probe cover seat securely over the retaining ring barb of the probe shaft.
3. Verify that the probe cover fits snugly.

NOTES
Failure to firmly install the probe cover may result in the probe cover becoming loose or disengaged during use. Unintended probe cover ejection can lead to patient injury.

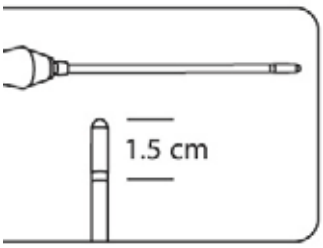
Do not insert the probe cover into the probe well.

Do not allow the probe tip to come into contact with the patient until the probe is placed in the measurement site. Before this, any contact between the probe tip and the tissue or other material may cause inaccurate readings.

CAUTIONS
Injury may occur as a result of patient movement during the procedure.

Do not insert the probe cover into the probe well.

4. Select the temperature parameter to activate a shortcut to the ***Monitor Setup > Temperature*** screen.
5. Select ***Measurement Site***. Check that the temperature area displays ***Rectal***. If this is not displayed, reselect the measurement site.



6. Separate the buttocks with one gloved hand and gently insert the probe tip according to hospital protocol – but no further than 1.5 cm (0.6 inches) for adults (less for infants and children).

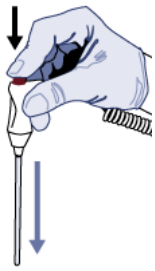
   WARNINGS

   If the tip is inserted too far, patient tissue damage may occur and the probe tip may not have good contact with tissue. Use of a lubricant on the probe cover is optional.

   Before performing rectal temperature measurement on neonates and children, check hospital policy whether it is allowed and with what conditions.

7. Always hold the probe in place, maintaining tissue contact until temperature is complete. Do not allow the patient to reposition the probe.

8. When the predictive measurement is complete, the result is captured to patient data automatically. If you question a reading, select the snail icon to switch to monitor mode.
9. When the monitor mode temperature measurement has stabilized, select ***Snapshot*** to create a snapshot and remove the probe from the patient.



10. Eject the disposable probe cover by firmly pressing the ejection button on the top of the probe. Then remove gloves.

    CAUTION

    To prevent cross-contamination, properly dispose of the probe cover and gloves when the measurement is complete.

11. Place the probe in the probe well. Once you place the probe in the probe well, the temperature values will be cleared in 1 to 30 minutes, depending on the measurement expiration time setting.

Welch Allyn temperature calibration and self-checks

When the monitor is powered on, the monitor automatically calibrates the temperature circuit to account for ambient room temperature.

NOTE

If large changes occur in the ambient temperature, the temperature system displays a technical error message. Turn the unit power off and on again. Note that the patient will be discharged and non-default settings cleared when the monitor is turned off. If the unit is not turned off after this temperature error message, the temperature measurement may not be accurate.

Welch Allyn temperature specifications

Units of measure	°Celsius (C) or °Fahrenheit (F)
Patient temperature	Minimum: 26.7° C (80.0° F) Maximum: 43.3° C (110.0° F)
Monitor mode accuracy	±0.1° C; ±0.2° F (when tested in a calibrated liquid bath in monitor mode or with a blackbody calibration tester); meets ASTM E1112, Table 1, in range specified) NOTE If large changes occur in the ambient temperature, the temperature system can be recalibrated by cycling the monitor's power using the **On/Off** button.
Temperature measurement time	Times are approximations only.
Oral	Approx. 4 -6 sec
Adult axillary (18 years and older)	Approx. 12 - 15 sec
Pediatric axillary (17 years and younger)	Approx. 10 -13 sec
Rectal	Approx. 10 -13 sec

NOTE
Use only Welch Allyn probe covers on the Welch Allyn temperature probes. The size, shape, and thermal characteristics of the probe covers can affect the performance of the probe. Inaccurate readings or retention problems may occur unless Welch Allyn temperature probes and Welch Allyn probe covers are used. Refer to the VC150 supplies and accessories document for reorder part numbers.

Patent information

Welch Allyn patents

For patent information, please visit www.welchallyn.com/patents

Troubleshooting

Problem	Cause	Solution

Temperature readings are lower than expected or reading is not obtained.	• The measurement may be affected by external influences.
	• The probe may not be in consistent tissue contact.
	• The probe may be incorrectly positioned.
	• Incorrect probe covers are used.
	• The axillary position of the probe may be too low to obtain a predictive measurement or the probe tip may be exposed to air through the back of the axilla.
		• Eliminate external influences caused by ambient air temperature or the intake of any liquids or physical matter by mouth before taking a measurement.
		• Verify the temperature probe is correctly positioned for the site being measured:
		  • Oral measurement: Place the thermometer tip in either the right or left sublingual pocket (heat pocket) at the base of the tongue. Have the patient close his or her lips over the probe. Continue to hold the probe in place, as motionless as possible until the final reading is obtained.
		  • Axillary measurement: Insert the probe in the patient's axilla, making sure the tip of the probe is in contact with the skin and positioned as close as possible to the axillary artery with the patient's arm held close to his/her side.
		  • Rectal measurement: Insert the probe, using current hospital technique for penetration.
		• Use Welch Allyn oral/axillary or rectal probe covers on the Welch Allyn temperature probe. Refer to the VC150 supplies and accessories document for reorder part numbers.

Repeated error messages appear when taking a rectal temperature.	• The lubricant applied to the probe cover is too thick, reducing the heat transfer from the patient to the probe. • The lubricant is too cool. • The probe may not be in consistent tissue contact.	• Do not over-apply lubricant to the probe. • Allow the lubricant to warm to room temperature before application to the probe cover. • To take an accurate rectal temperature reading, insert the probe tip according to hospital protocol – but no further than 1.5 cm (0.6 inches) for adults, less for pediatric patients. If the tip is inserted too far, damage may occur and the probe tip may not have good contact with tissue.

Problem	Cause	Solution
Temperature readings do not register on hypothermic patients.	Wait until the predictive measurement is complete. Then switch manually to monitor mode. Allow the temperature values to stabilize before recording the temperature. It will continue to monitor the patient's temperature until the probe is removed from the patient (the temperature reading will change as soon as the probe is removed from the patient; record the temperature displayed at the prescribed time before removing the probe from the patient).	The monitor does not beep to indicate a final reading. Leave the probe in place for the same length of time as required by standard hospital procedure for taking a continuous (monitor) temperature measurement.

Cleaning

Refer to "Cleaning" on page B-4 for instructions for cleaning and disinfecting Welch Allyn device and its accessories.

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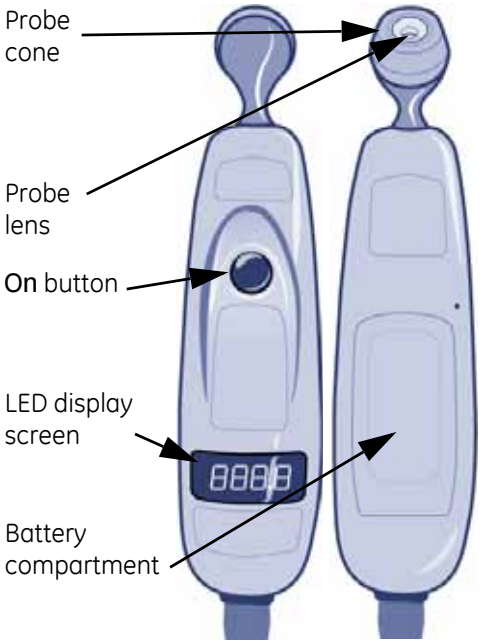
12 Exergen temperature

Description

The monitor can use the Exergen Temporal*scanner* technology if it has the Exergen temperature parameter (temperature parameter displayed on the screen and Exergen connected to the monitor USB port).

Temporal*scanner* technology provides a method of temperature assessment based on infrared measurement of the thermal radiation of the skin. The temporal artery is used as a sampling site because of its relatively constant perfusion rate. While the scanner senses temperature from the area of the temporal artery, it can optionally report temperature readings referenced to either central arterial temperature or oral temperature.



Temperature values are shown in degrees Celsius or Fahrenheit on the monitor screen and on the scanner's LED display screen. The LED display screen displays the temperature, but does not display the unit of measurement.

The preset unit of temperature measurement on the monitor screen and the Exergen LED display can be changed by service personnel only.

NOTES

Arterial temperature is close to rectal temperature, approximately 0.4° C (0.8° F) higher than oral temps. Expect larger differences at times, however, as the dynamics of thermoregulation favor the temporal artery method. Arterial temperature is the same temperature as the blood flowing from the heart via the pulmonary artery. It is the best determinant of body temperature, and unaffected by the artifactual errors and time delays present with oral and rectal methods.

The scanner takes a single instance of a temperature measurement. Exergen technology does not support continuous monitoring.

A monitor with the Exergen temperature technology configuration setting cannot perform Welch Allyn temperature measurements and vice versa.

Use this product only for its intended use as described in this manual.

Do not take temperature over scar tissue, open sores, or abrasions.

The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.

Do not autoclave. Please note cleaning and sterilizing procedures in this manual.

NOTES

Do not use the thermometer if it is not working properly, if it has been exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.

There are no parts that you can service yourself except for the battery, which you should replace when low by following the instructions in this manual. For service, repair, or adjustments, return your thermometer to Innokas Medical.

Never drop or insert any object into any opening, except for opening the battery cover as described in this manual.

The VC150 monitor can be used with two Exergen thermometer options:

- Oral calibration
- Arterial calibration

One version has been calibrated to report measurements referenced to core arterial blood temperature, while the other is calibrated to report measurements referenced to oral equivalent temperature.

Temperature measurement mode

Upon initiation of a measurement, the previous temperature measurement, if present, is cleared. A measurement is initiated when the user presses the **On** button on the scanner. The ***Temperature*** window on the monitor remains blank while a measurement is in progress. In measurement mode, a final temperature is displayed and an audible double tone sounds.

A measurement is terminated when one of the following occurs:

- The user releases the **On** button and final value is determined.
- A technical alarm is issued.

WARNINGS

Keep accessories out of patient's reach when not in use.

Do not allow the scanner to come into contact with open wounds or mucous membranes.

Keep the temperature scanner secured when it is not in use.

NOTES

Connect only one integrated Exergen TAT-5000S-USB scanner to the monitor.

If the Exergen scanner is not used regularly, remove the battery to prevent possible damage due to chemical leakage.

The scanner will issue an error code if a temperature determination is not possible, and the monitor will also indicate an error in the temperature window. In addition, at temperatures between 16.1° C and 26.7° C (61° F and 80° F), the scanner will display a value, and the monitor will indicate the value is out of range with a '----' in the temperature window.

Additional indicators

If the scanner is unable to take a temperature determination or has a low battery, the monitor will display a technical alarm on the monitor screen. Refer to "Technical alarm conditions" on page 4-10 for additional indicators on the scanner's LED window.

Sounds

There are three sounds associated with the Exergen temporal scanner parameter.

- Single tone: sounds upon detection of a temperature status alarm regardless of the state of alarm silence.
- Double tone: sounds at the completion of a temperature measurement that results in a final value.
- Audible selecting tone: Each fast click tone indicates a rise to a higher temperature. A slow selecting tone indicates that the scanner is still scanning, but not finding any higher temperature.

The VC150 will sound two beeps when a snapshot is automatically created after completion of a measurement.

Procedures for temperature determination

Familiarize yourself with the scanner

- To scan: Press and hold the **On** button. The scanner will continually scan for the highest temperature (peak) as long as the button is pressed.

  NOTE

  Be aware that if you accidentally press and release the **On** button without applying the scanner to a patient's forehead, the scanner will include this erroneous ambient room temperature value in patient data.

- To view the displayed temperature value: After taking a temperature measurement, the temperature value will remain on the scanner display for 30 seconds after button is released. If measuring room temperature, the temperature value will remain on the scanner display for 30 seconds.
- To restart: Press the **On** button to restart. It is not necessary to wait until the display is clear. The thermometer will immediately begin a new scan each time the button is selected.

Basics of using the temporal scanner

CAUTIONS

To prevent cross-contamination between patients, apply a fresh disposable cap on the probe or clean the Exergen between patients as instructed in "Cleaning the Exergen probe head and neck" on page B-6.

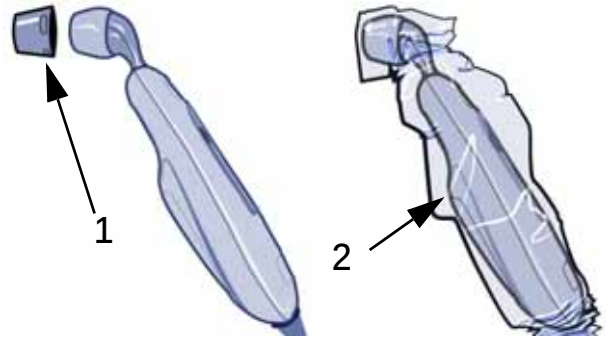
1. Confirm the temporal scanner is connected to the monitor. Refer to "Connecting USB accessories" on page 3-6 for more information.

   NOTE

   Be careful not to overextend the coiled cord of the scanner. Overextension can damage the scanner coil connector interfaces.

2. If needed, place a disposable cap over the probe head or a protective sheath over the entire scanner. Be sure to inspect the protective cover or sheath before every use to make sure the cover or sheath is defect free, contamination free, and installed properly with a snug fit. When using a protective disposable cap or sheath, always use a new protective cover or sheath when taking a measurement on a different patient.

Item	Name
1	Protective disposable cap
2	Protective sheath

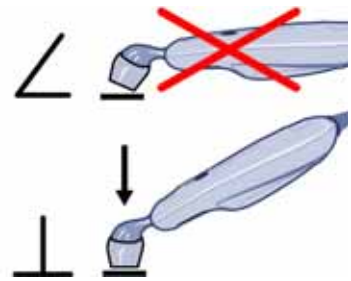


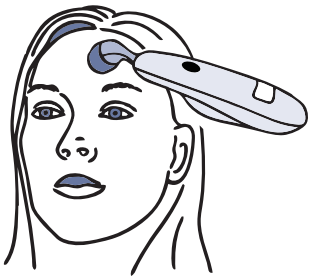
CAUTION

Patient movement during temperature measurement may result in patient injury.

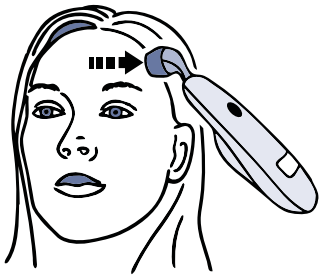
3. Brush patient's hair aside if covering the temporal artery area or the ear area.

4. Gently place the scanner on the center of forehead, press and hold down the **On** button on the scanner. Keep the scanner head in flush contact with the skin while sliding.





5. While still pressing the **On** button, slide the scanner slowly and gently straight across forehead to the patient's hair line, ***not*** down on the cheek.



6. Brush patient's hair away if covering ear. Keeping the button selected, lift probe from forehead, gently touch behind ear halfway down the mastoid process and slide down to the soft impression behind the earlobe.

7. Release the **On** button and read the temperature. When the determination is complete, an audible double tone sounds and the temperature displays on the scanner's LED display screen and on the monitor. The reading will remain on LED display screen of the scanner for 30 seconds after the button is released. The reading will remain on the monitor's display for 1 to 30 minutes, depending on the monitor configuration.

8. If you placed a protective disposable cap or scanner sheath on the scanner, dispose of the protective disposable cap or scanner sheath according to the applicable waste control regulations of your facility.

CAUTION

To prevent cross-contamination, properly dispose of the disposable cap when done with its use.

9. Clean the Exergen scanner as instructed in "Cleaning the Exergen sensor lens" on page B-6.

CAUTION

Failure to clean the scanner between patients may increase the risk of cross-contamination.

Exergen temperature specifications

Units of measure	°Celsius (C) or °Fahrenheit (F). Defined by purchased Exergen scanner.
Range	
Measurement mode	Max: 43° C (110° F) Min.: 16° C (61° F)
Accuracy	±0.1° C (±0.2° F) complies with EN 12470-5
Predictive mode	Not applicable
Monitoring mode	Not applicable
Operating environment (ambient)	16° to 40° C (61° to 104° F)
Arterial head balance range for body temperature[1]	34.5° to 43° C (94° to 110° F)
Resolution	0.1° C or 0.1° F
Response time	Approximately 0.04 seconds, typical
Calibration	Oral or Core

[1] Automatically applied when temperature is within normal body temperature range, otherwise reads surface temperature.

NOTE

Use only Exergen probe covers. The size and shape of the probe covers can affect the performance of the scanner. Inaccurate readings occur unless the proper probe covers are used. Refer to the VC150 supplies and accessories document for reorder part numbers.

Exergen scanner battery specifications

Capacity	One 9 volt alkaline
Battery life	Approx. 15,000 readings (When scanning for 5 seconds and reading the temperature display for 2 seconds before turning thermometer off.)

Patent information

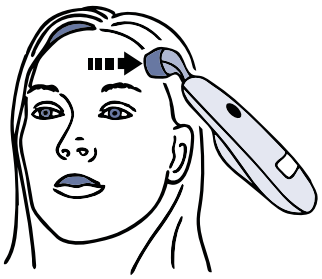
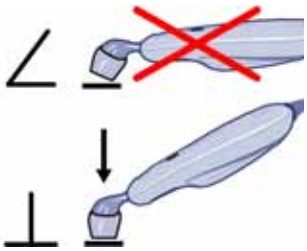
Exergen patents

For patent information, please visit www.exergen.com/patents

Troubleshooting

Problem	Cause	Solution

Unable to take a measurement from the patient's forehead.	The patient has bandages or pressure dressings covering the forehead or abrasions, burns, or sweat on the forehead.	Use alternate measurement sites:
		• If accessible and dry, measure on the area behind the earlobe only.
		  • If the temporal artery (TA) area has been traumatized by burns or lacerations, is completely covered with dressings, or the head has suffered surgical or accidental trauma, the temperature can be obtained from the alternative site behind the earlobe. As with diaphoresis, the perfusion will be high in the presence of head trauma.
		  • Behind the earlobe is the alternate site because sweat causes evaporative cooling of the skin on the forehead and may produce a false low reading. During diaphoresis, the area on the head behind the earlobe will always exhibit the high blood flow necessary for the arterial measurement.
		  • Measurement behind the earlobe is not the *sole* recommended area because the arterial branch is deeper behind the earlobe than at the temple, and under normal conditions it is less accurate because of its variability. But under diaphoretic conditions, the blood flow behind the earlobe is as high as at the TA, making it as accurate as the TA, but only during diaphoresis or with head trauma as previously mentioned.
		• If the temporal artery or the area behind the earlobe is not accessible and dry, choose one of the following alternate temperature measurement sites:
		  • Femoral artery: scan across the femoral artery following the crease in the groin.
		  • Lateral thoracic artery: slowly scan side-to-side in the area, midway between the axilla and the waist. Mainly used for children.

Problem	Cause	Solution
Unable to get an accurate measurement.	The patient is agitated or combative.	Consider using the alternate sites: femoral artery or lateral thoracic.
Possible false reading.	The patient's forehead is in a direct draft from a vent or fan.	Remove the source of the draft. Each 10° difference in ambient temperature can cause a 1° error in the reading.
	The thermometer is in a different ambient temperature than patient (e.g., window ledge directly exposed to hot sun or cold weather, or in direct line of air conditioning or fan).	Store the scanner at the same ambient temperature as the patient for at least 20 minutes before taking a temperature measurement. Each 10° difference in ambient temperature can cause a 1° error in the reading.
Scanner readings are not comparable to current/traditional methods.	Arterial temperature is close to rectal temperature, approximately 0.4° C (0.8° F) higher than oral temps.	Expect larger differences at times, as the dynamics of thermoregulation favor the temporal artery method.
Scanner readings are lower than current/traditional methods; false low readings.	• A patient's temperature measured with the scanner is normally not appreciably lower than oral temperature. Lower temperatures are usually caused by improper scanning techniques. • A dirty scanner lens may result in inaccurate measurement determinations. • Both a sweaty forehead and wet behind ear. • Multiple readings can cool the skin, so if you take another measurement immediately, expect a slightly lower reading. • The button was released before the measurement was complete.	• Slide the scanner straight across the forehead, not down the side of the face. Do not scan too quickly.  • Keep the probe cone flush on the skin. • Clean the lens. • Return when patient stops sweating. • Keep the button pressed down while scanning.  • Refer to "Basics of using the temporal scanner" on page 12-5 for user instructions.
The measurement appears on the scanner window, but does not register in the monitor.	• The scanner's connector is not secured to the monitor. • The scanner's battery cover is not secured. • Loss of electrical contact between the scanner and the monitor (e.g., corrosion on the connector inside the scanner). • The monitor is not configured to interface with an Exergen scanner.	• Confirm the scanner's connector is secured to the monitor. • Confirm the scanner's battery cover is secured. • Contact service.

Problem	Cause	Solution
Scanner readings are higher than current/traditional methods; false high readings.	• The forehead is covered during a temperature measurement. • Temperatures measured with the scanner may be higher than your current method, especially if you are familiar with oral or axillary temperatures.	• Any covering, hair, hat, bandages, etc., would prevent the heat from dissipating, causing the reading to be falsely high. Only measure skin that is exposed to the environment. • Oral and axillary temperatures can be misleadingly lowered due to patient activity such as mouth breathing, drinking, tachypnea, coughing, talking, etc., and periods of vasoconstriction during the fever process. Any or all of these conditions may even mask fevers that the scanner will detect.

Batteries

Refer to "Maintenance" on page B-1 for details on storage, care, replacement, and disposal of batteries for the monitor and the Exergen temporal scanner.

Cleaning

Refer to "Cleaning" on page B-4" for details on cleaning and disinfecting the Exergen temporal scanner.

13 Battery

Description

The monitor uses a rechargeable Lithium-ion (Li-Ion) battery that consists of Li-Ion cells that can be charged at any time without reducing its charge capacity. The battery reports its condition to the monitor and this is displayed by battery indicators on the monitor screen. The monitor is designed to always derive its power solely from the battery; and the battery is being charged whenever the external DC charger is connected (refer to "Product specifications" on page 2-19).

Description	LED
Connected to mains. When a green LED is: • On: Power cable is connected to mains • Off: The power cable is disconnected	
Battery OK. When power LED is: • On: Battery full • Blinking (every 2 seconds): Battery charging • Off: No battery / Low charge	
Low battery. When orange LED is: • Off: OK state • On: Charge remaining for at least 10 NIBP measurements. • Blinking fast (every 0.2 seconds): Battery error / No battery • Blinking slow (every second): Battery charge for 5 minutes or less of unit operation time remaining	
State of operation. When a green LED is: • On: The monitor is switched on • Off: The monitor is switched off	

NOTES

- Due to moisture condensation risk, the monitor has to warm up to room temperature after transportation or storage.
- Only trained and authorized service person may uninstall and install the battery. The monitor cannot be used before the battery is installed.
- The monitor is designed to operate only when the battery is installed in the monitor.
- When the monitor's battery has been completely discharged, the monitor must be connected to an external power supply before monitoring can resume.
- Service must unplug the battery before transport or storage.

WARNINGS

Use only a battery type that has been specified for this monitor. Do not use a damaged or leaking battery. Other batteries may not provide the same operating time and may cause unexpected monitor shutdown. Other batteries may be incompatible with the internal charger and may cause battery acid leakage, fire, or explosion.

Do not disassemble, modify, crush or destroy the battery pack. Doing so can cause battery fluid leakage, heat generation, burns, fire, and/or explosion.

Do not incinerate the battery or store at high temperatures. Doing so may cause the battery to explode.

Do not short-circuit the battery terminals by directly connecting the metal terminals together. Be certain that no metal objects (e.g., coins, paper clips, etc.) touch both battery terminals simultaneously. Doing so can cause the battery to overheat and/or explode, resulting in possible caustic burns and/or battery damage.

Charge the battery pack with the monitor's internal charger only. Use of an unrecommended charger may cause battery fluid leakage, overheating of the battery, or may cause the battery to explode.

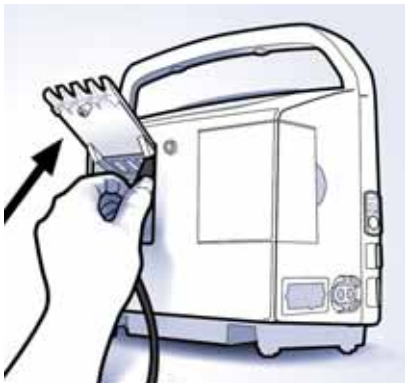
The battery will completely discharge if the monitor is stored for a prolonged period of time with the battery left inside and not periodically recharged. Configuration settings may be lost as a result.

Battery charging

Prior to each use, inspect the power cord to ensure proper connection and condition.

With external DC power connected, the battery charge icon and an LED on the power on/off button indicate that the battery is charging. This indicator remains active whether the unit is on or off. A tone sounds whenever the DC charger is connected/disconnected.

Battery charging will take place as long as the monitor remains connected to an external DC power source.

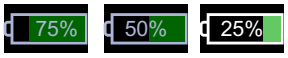


- Charge the battery pack for 8 hours before first use or after prolonged periods of storage.
- If the monitor is idle for extended periods, it should be fully charged at least once a week to ensure optimum performance. If the monitor is to be stored for longer than one month, first charge the battery and then have service to unplug the battery connector.

- The battery pack should be charged before use, because a charged battery loses charge when left in storage. Charging is done automatically by the monitor when the external DC power is connected.
- The battery pack should be charged at room temperature, 5° C to 40° C (41° F to 104° F).
- You can charge the battery pack at any time. You should not wait until battery is fully discharged.
- Keep the monitor connected to a DC power supply whenever possible. Do not allow the battery to become completely discharged.
- Keep the monitor plugged in when not in use to ensure maximal battery charge.
- A fully charged battery will power the monitor for up to 8 hours in a heavy-use scenario and up to 11 hours in a light-use scenario (refer to "Monitor battery specifications" on page 13-6 for details). If the monitor is being used very intensely, the operation time may be less than mentioned before.
- To ensure full charge cycles, replace only with a recommended battery.
- Replace the battery every three years. If the monitor displays a low battery soon after charging or is unable maintain charge, contact service for battery replacement.

Battery charge level

When the monitor is not connected to an external power supply and a green battery indicator is displayed on the screen, the battery is fully or sufficiently charged to perform 11 or more NIBP measurements.



The green battery indicator displays the remaining power as a percentage.

A red battery indicator and low priority battery alarm message on screen mean that the battery is running out and the monitor may perform approximately 10 NIBP measurements. Use of the printer should be avoided. When there are five minutes of monitor operation time available, both a red battery indicator and a high priority battery alarm message are displayed on the screen. The battery power level is low and the monitor must be connected to an external power supply. Printing and NIBP measurements are no longer possible, but network communication is still possible.

When the monitor is connected to the mains and the battery is charging, a animated battery charge indicator is displayed on the information area of the screen. The battery will be charged in about 8 hours if the monitor is being used at the same time. If the monitor power is off, the battery will be charged in about 4 hours. Each time the monitor is connected to or disconnected from mains, an audible signal sounds.

If the monitor is turned on without an installed battery, a missing battery indicator is displayed on the screen and the monitor will not allow any operation. If the battery becomes faulty during operation, a missing battery indicator is displayed on the screen. If this icon appears on the screen, the monitor must not be disconnected from an external power supply.

Storage, care, and replacement of batteries

Refer to "Maintenance" on page B-1 for details on storage, care, and replacement of batteries for the monitor and the Exergen temporal scanner.

Disposal of batteries

Refer to "Maintenance" on page B-1 for details on disposal of batteries for the monitor and the Exergen temporal scanner.

Battery alarms

Battery low

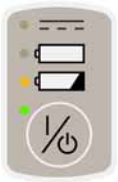
When battery charge for at least 10 NIBP measurements remains:

- Battery icon will change to red when low priority battery alarm is triggered.
- The monitor continues to operate normally.
- A low priority alarm is displayed.
- An orange LED is displayed above the **On/Off**-button.

NOTE

It is strongly recommended that you plug the monitor into external DC power when the low battery alarm is active.

When battery charge for about 5 minutes or less of unit operation time remains:



- A red battery indicator is displayed on the screen and an orange LED above **On/Off**-button starts to blink slowly.
- A high priority alarm message is displayed.
- The user is not able to initiate:
  - any new NIBP determinations of any type
  - any printouts

NOTE

Monitor cannot be restarted when battery charge is critically low. This means that if a high priority ***Low battery*** alarm is active and monitor is shut down, it cannot be restarted before the charger is plugged in. This is to protect the battery pack.

Monitor battery specifications

Capacity	5.2 Ah Li-Ion battery
Battery run time	Up to 11 hours with a usage scenario of: • NIBP determinations every 15 minutes • SpO_2 or temperature parameter not active • WLAN off Up to 8 hours with a usage scenario of: • NIBP determination every 5 minutes with an adult cuff • SpO_2 and temperature parameter actively measuring • WLAN on The above battery run times are valid for a new battery and depend heavily on display brightness settings. After approximately 300 full charge and discharge cycles, the capacity of the battery is reduced to 70 percent of its original rating.
Charge time	Approximately 4 hours from full discharge when the monitor is off. Approximately 4 hours when the monitor on.

Troubleshooting

This section discusses potential difficulties and suggestions for resolving them. If the difficulty persists, contact service or your local Innokas Medical representative. The service manual, which is for use by service personnel, provides additional troubleshooting information.

Problem	Cause	Solution
The monitor cannot be turned on.	• Is the battery missing? • Is the battery discharged?	• Check that the battery is installed. • Charge the battery. Refer to "Battery charging" on page 13-3.
The battery does not work or does not last very long.	• Has the battery been charged? • Has the battery been in storage or a nonuse condition for a few months? • Is the battery installed properly? • Was the battery over-discharged when it was last used? • Battery may be bad.	• New batteries must be charged before use. Refer to "Battery charging" on page 13-3. • Bad battery must be replaced. Contact service.

Problem	Cause	Solution
The battery will not charge.	• Are you trying to charge the battery in unusually cold or hot temperatures?	• Charging the battery should be done at a basic room temperature of 10° C to 35° C (50° F to 95° F). Slowly bring the battery to the basic room temperature before charging. Batteries can be fully charged only when their internal temperatures are between 5° C to 40° C (41° F to 104° F).
 The battery missing indicator appears on the screen.	There is some fault in the battery.	• Keep the monitor connected to an external power supply. All operations of the unit are accessible except clinical mode. • Write down the error message. • Discontinue all measurements and store data in hospital network. • Turn the monitor off. • Contact service.
The battery low indicators remain lit.	The battery may be defective and unable to recharge.	Try to charge the battery again. If unsuccessful, replace the battery.

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14 Default setup

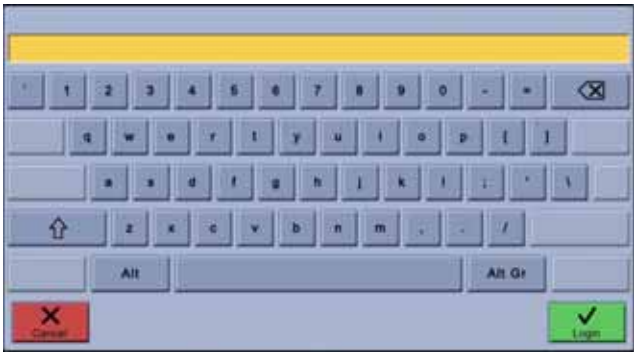
Introduction

Password-protected ***Default Setup*** is intended for someone at the hospital or care unit that has the training and authority to configure default settings for the monitor. Obtain the password from service.

> WARNING
> When you are done with the configuration, remember to press the home icon to save settings and exit the ***Default Setup***. Failure to do so allows change of settings by unauthorized users.

1. Select ***Login Default Setup*** in the ***Monitor Setup > Advanced*** screen.

2. Enter the password and select ***Confirm***.



3. Adjust the settings for ***General***, ***Alarm Defaults***, ***Visual Settings*** or ***Measurement Settings***.

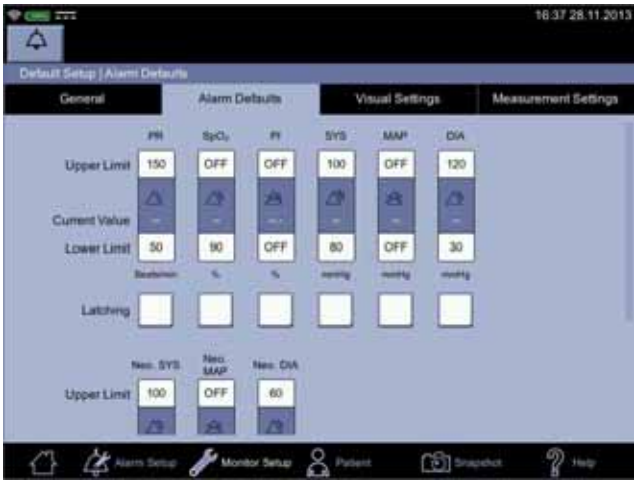
General

General screen items can be set in ***Monitor Setup > Advanced > Default Setup > General***. These settings affect all applicable monitor screens. Availability of the choices may vary due to SpO_2 technology and other purchased options.

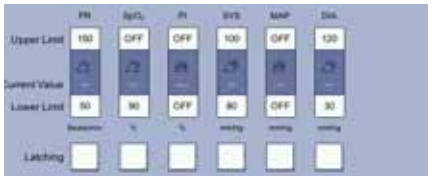
General settings	Description
Minimum Alarm Volume	Minimum level of alarm sound.
System Time	Current date and time.
Measurement Expiration Time	Amount of time for NIBP and temperature measurement values to remain on screen after the measurement is completed.
Automatic Discharge and Standby After	Idle period after which the monitor will enter standby state.
Snapshot upon NIBP Completion	Current values for SpO_2, Welch Allyn temperature (monitor mode), RR or RRa, and extra parameters by Masimo SpO_2 are stored as a snapshot upon completion of NIBP determination.
Use low priority alarm tone	Determines whether low priority alarms are audible.
Monitor Profile	Selection for active profile (***Spot-check*** or ***Monitoring***) upon start-up.
Oximetry Graph	Type of graphic presentation of SpO_2 data in the Graph area.

Alarm defaults

Parameter-specific upper and lower limits may be set up or enabled/disabled in the ***Default Setup > Alarm Defaults*** screen. Limits set here will remain even if the monitor is restarted. ***Alarm Defaults*** screen settings provide a starting point that the user can then adjust in ***Alarm Setup*** as she/he wants to.



Change/enable/disable a single limit



1. Select ***Monitor Setup > Advanced > Login Default Setup > Alarm Defaults***.
2. Select a single alarm limit.

3. Enter a value to set up or adjust a limit. A value between upper and lower limits is the ***Current Value*** of the parameter (the sensors must be attached to the monitor). It is provided to assist in setting up or adjusting a limit.

NOTE

Adjust alarm limits cautiously.

4. Select whether the alarm is latching or non-latching. The table below summarizes the differences.

Non-latching alarms	Latching alarms
When an alarm limit is triggered, visual and audible alarms remain active until alarm condition ends or times out, whichever takes place first.	When an alarm is triggered, visual and audible alarms remain active even after the alarm condition disappears. Audible and visual alarms will cease only after acknowledging the alarm.

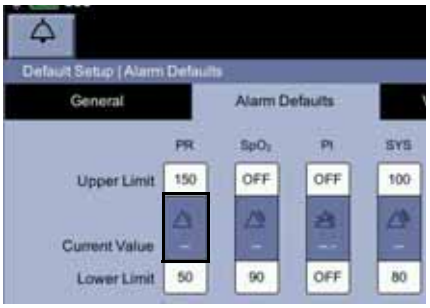
WARNING

SpO_2 and Pulse Rate alarms are latching by default to prevent a situation where alarms disappear from the display if a patient under monitoring becomes asystolic. Consider carefully the possible impact if setting these alarms to non-latching.

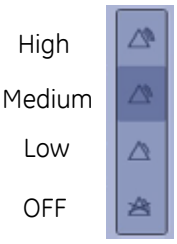
5. To disable a limit, keep selecting the backspace icon until the numeric field is blank.
6. Select ***Confirm*** to confirm the change or select ***Cancel*** to cancel the change.
7. Adjust the limits for each patient, especially for neonates and children.
8. When you are finished with alarm setup, select the home icon to save the settings and return to clinical mode.

Changing priority for the limit

1. Select ***Monitor Setup > Advanced > Login Default Setup > Alarm Defaults***.



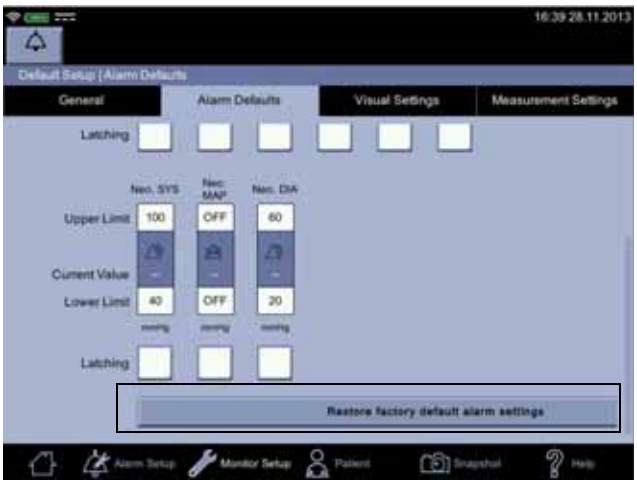
2. Select the middle section of a limit bar to adjust priority for the alarm limit. A disabled limit is displayed as grayish-blue and cannot be modified in clinical mode. An enabled limit is displayed in dark blue and can be modified in clinical mode.



3. Select the required alarm priority level in the pop-up image. After the selection, the pop-up disappears.

NOTE

Restore factory default alarm settings will remove all custom alarm settings and return to the alarm settings set by the manufacturer.

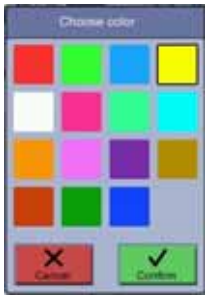


4. Configure Nellcor or Masimo options, if necessary. Refer to "Nellcor SpO_2 configuration" on page 9-27 or "Masimo rainbow® SET® SpO_2 configuration" on page 8-25 for more information on these options.

5. Select the home icon to save the settings and return to clinical mode.

Visual settings

Default colors and parameters displayed on the home screen in clinical mode can be modified in the ***Monitor Setup > Advanced > Login Default Setup > Visual Settings*** screen.



1. Select an item underneath ***Parameter colors*** to change the color of that parameter on the screen.
2. Select ***Confirm*** to confirm the change and save the settings.
3. Select ***Waveform parameters*** to display parameter data. You can select one, a few or all waveform parameters (RR, RRa, SIQ, SpO_2).
4. Select items in ***Show*** that you want to display on the home screen in clinical mode.

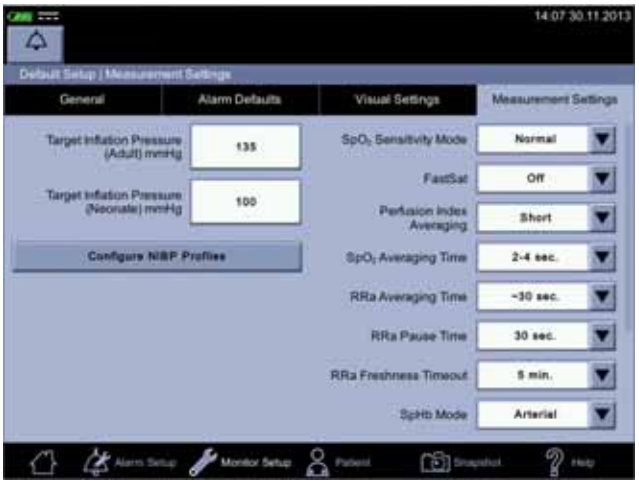
NOTE

The visual settings you just selected will be applied to the home screen immediately. If you deselect an item in the ***Monitor Setup > SpO_2*** screen, it will not be displayed on the home screen. If the monitor is restarted, the monitor will revert to the default settings.

5. Select the home icon to save changes in the default settings and return to clinical mode.

NIBP profile setup

1. Select ***Configure NIBP Profiles*** in the ***Monitor Setup > Advanced > Login Default Setup > Measurement settings*** screen. A pop-up screen will appear after the selection.



Screen with Masimo

2. Select an NIBP profile name.

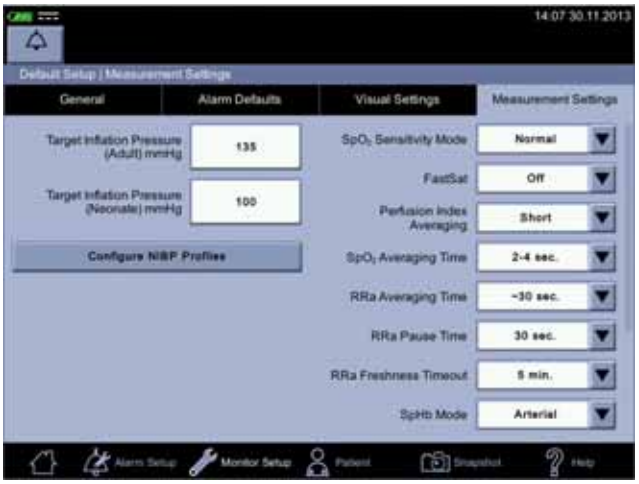
3. Enter a name for the profile and select ***Confirm***.
4. Enter all interval values one by one, selecting ***Confirm*** after each entry. You can cancel the process with ***Cancel***.

5. Rename and reset other profiles if necessary.
6. If a profile name is incorrect, select that profile name. Then use backspace to delete the old profile name and enter the correct name.
7. Select ***Confirm*** when all settings are complete.

When you are ready with the configuration, select the home icon to save the settings and exit the configuration mode. When the home icon is selected, the system will return to clinical mode.

Masimo default settings

Refer to "Masimo rainbow® SET® SpO_2 configuration" on page 8-25 for more information on optional Masimo features available if licenses for these were purchased with the unit or afterwards.



A Connections

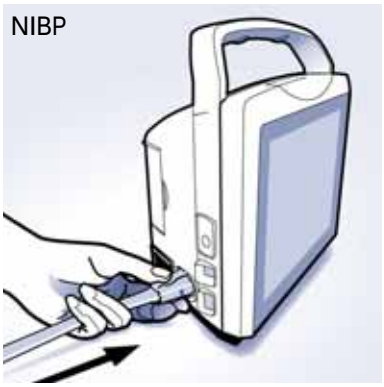
Connections

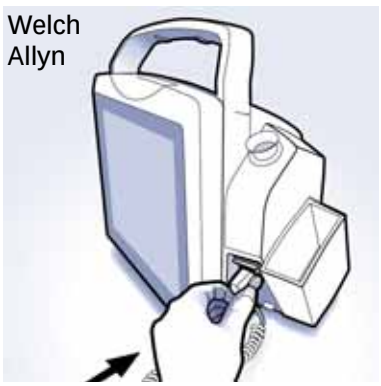
CAUTION

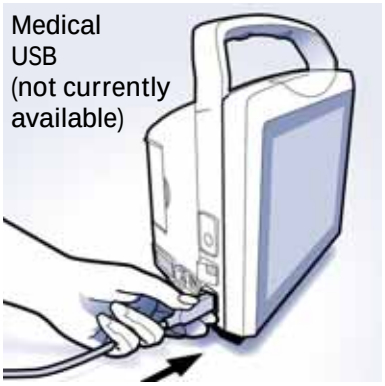
Auxiliary equipment connected to the VC150 vital signs monitor will result in the formation of an electromedical system, and thus, must comply with the requirements of IEC 60601-1-1. All host port signals except for USB-B are ***non-isolated*** and should be connected to equipment conforming to IEC-60601-1 or configured to comply with IEC 60601-1-1 ***only***. Do not connect unapproved devices to the monitor.

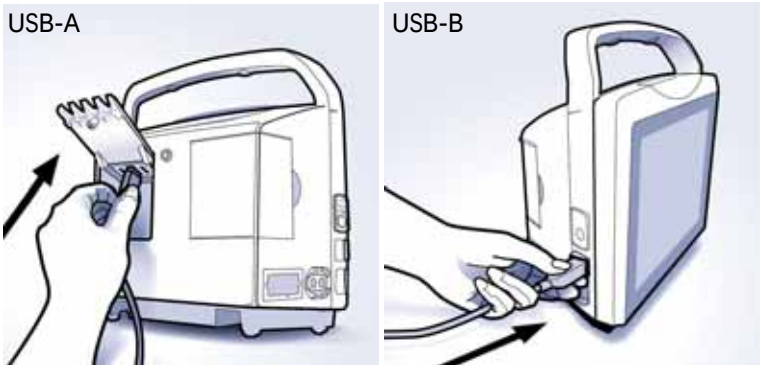
Contact your Innokas Medical representative for the VC150 Hostcomm protocol specification.

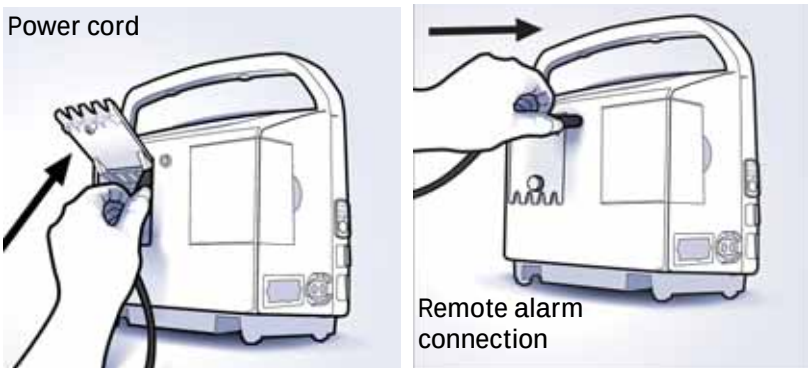
- The monitor provides connections for NIBP, SpO_2, USB-B, Welch Allyn, three regular USB-A connections, remote alarm and a power cord. One port is reserved for a future Medical USB connection. This port is currently not available.











Refer to "Setting up temperature connection" on page 3-4 for instructions on how to plug in the Welch Allyn temperature probe.

When a USB-A cable is connected, the monitor tries to find an external USB device. When a USB-B cable is connected, the monitor can be connected to a PC.

NOTE

If you want to have strain relief on USB-A cable, ask service to perform this.

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B Maintenance

Service and parts

There are no user-serviceable parts or replaceable fuses inside the monitor. Refer all service work to service personnel.

If the product fails to function properly, or if assistance, service or spare parts are required, contact Customer Support. Before contacting Customer Support, try to duplicate the problem and check all accessories to ensure that they are not the cause of the problem. If you are unable to resolve the problem after checking these items, contact Innokas Medical. Prior to calling, please be prepared to provide:

- product name, model number, and serial number
- a complete description of the problem

If repair parts or service are necessary, you will also be asked to provide:

- the facility's complete name, address
- a purchase order number if the product needs repair or when you order spare parts
- the appropriate part number for spare or replacement parts

Maintenance

An effective maintenance schedule should be established for your monitoring equipment and reusable supplies. This should include monthly visual inspection as well as general monthly cleaning. The maintenance schedule must comply with the policies of your institution’s infection control unit and/or biomedical department.

WARNINGS

Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system may cause damage to the monitor and/or the accessories, leading to impaired performance and/or inaccurate readings.

NOTES

- Discard single-use accessories after use.
- There are no user-performed maintenance or calibration procedures for Welch Allyn thermometry.
- Innokas Medical does not, in any manner, assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the device.

User maintenance schedule

Maintenance procedures performed by the daily caregiver help keeping the monitor uptime as high as possible. The following maintenance schedule is recommended.

Maintenance procedure	Schedule
Visual Inspection	Monthly or as usage requires.
Cleaning	Monthly or as usage requires.
Speaker test	Monthly or as usage requires.

Visual inspection

Check following items and contact service if any of these checks fails.

Inspection item	Notes
Any signs of physical damage to: • the monitor case • integrity of the display • the power membrane button	Do not use the monitor if damage is determined. Have service replace any damaged parts of the unit. NOTE If parts of the display are not legible or appear corrupt, do not use the monitor. Have service replace the display. If the touch panel appears inaccurate, refer to "Touch screen recalibration" on page 3-9.
Loose connectors or frayed cables in external connections	
Safety labels and inscription on the device clearly legible	
Integrity of hoses and cuffs	When the pneumatic integrity of any NIBP cuff and hose is in doubt, replace the cuff and hose and discard the questionable accessories.
Speaker test	1. Switch the monitor on and wait to hear two beeps. 2. Unplug and plug the power supply cord. A chirping sound is heard. If you do not hear either of these, contact service.

WARNING
Do not use damaged sensors, cables, or connectors.

Calibration

User can only recalibrate the touch screen. Refer to "Touch screen recalibration" on page 3-9, if necessary. No other user-lever calibrations are required.

Cleaning

List of approved cleaning agents

Use only these cleaning agents to clean the monitor unit or the Welch Allyn probe well. Periodically, Innokas Medical evaluates additional cleaning agents for compatibility with the monitor. If your cleaning agent is not listed in this section, contact your Innokas Medical representative to determine if additional information is available.

List of approved cleaning agents for VC150 monitor and accessories (except Welch Allyn SureTemp® Plus)			
Cavicide® Surface Cleaner/Disinfectant	Sagrotan® Alternative	Sani-Cloth® HB	Sporicidin®
Virex 256	Water (distilled)	Windex Blue	

List of approved cleaning agents for Welch Allyn SureTemp® Plus	
Probe well	Warm water and a mild detergent solution.
Thermometry probe	70% Isopropyl alcohol 10% bleach solution and Cavicide® or equivalent.

NOTES

The touch screen surface is made of PET (polyethylene terephthalate) and must not be cleaned with any solvent or any alkaline cleaning agent.

If you want to use other cleaning agents than those specifically approved and listed in this section, you can do it at your own risk. However, bear in mind that using non-approved cleaning agents voids the product warranty on all monitor parts that may come in touch with non-approved cleaning agents. If you still want to use a non-approved cleaning agent, first test it on the corner of the touch screen, not on the whole screen. Remember to wipe off possible residues or stains with a cloth dampened with water.

Prohibited cleaning agents

Never use the following cleaning agents on the monitor, monitor accessories, or the Exergen temporal scanner:

- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Alcohol-based cleaning agents. (However, an alcohol-based cleaning agent can be used on the Welch Allyn temperature metal probe and plastic section of the probe, Exergen scanner's lens, probe head and metal neck only.)
- Petroleum-based cleaning agents
- Any type of solution that contains ammonium chloride, conductive solutions, wax or wax compounds
- Sodium salts

NOTE

Never autoclave or steam clean the monitor, cuffs, or accessories.

Cleaning schedule

To prevent cross-contamination, clean exterior surfaces of the monitor, monitor accessories, and reusable sensors on a regular basis in compliance with your institution's infection control unit and/or biomedical department's local policy.

Procedure

WARNINGS

Always shut down the monitor and disconnect it from the electrical network before any cleaning procedure.

Prior to using a cleaning agent, read the instructions for use and adhere to provided safety precautions.

Never pour or spray water or any cleaning solution on the equipment or permit fluids to run behind switches, into connectors, into the printer, or into any ventilation openings in the equipment. Do not let fluid "pool" around connection pins. Do not immerse the monitor, the sensors or the hoses in liquids.

Use of unapproved cleaning agents can cause case damage resulting in unintended fluid ingress and a potential for compromising electrical safety.

Do not use steam, heat, chemical or gas sterilization on the monitor or its accessories. *Do not* autoclave the accessories.

NOTE

Clean the monitor and sensors according to local policies.

Cleaning the exterior surfaces

Disconnect the monitor from AC power before cleaning or disinfecting its surface. The exterior surfaces of the monitor, monitor accessories, and temporal scanner may be cleaned with a lint-free cloth, dampened with a cleaning agent listed in "List of approved cleaning agents" on page B-4. Wipe off all cleaning solutions with a clean, dry cloth and let air dry for at least 15 minutes.

NOTE

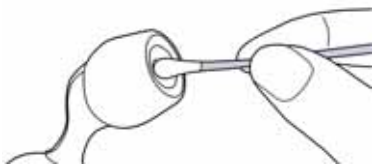
Exergen temporal scanner only: Alcohol-based cleaning agents can be used on the scanner's lens, probe head and metal neck only.

Cleaning the screen

To clean the VC150 monitor screen or the Exergen screen, use a soft, clean cloth dampened with a cleaning agent listed in "List of approved cleaning agents" on page B-4. Never spray the cleaning agent directly onto the display.

Cleaning the Exergen sensor lens

Dirt, greasy film, or moisture on the scanner lens will interfere with the accuracy of the temperature reading. Regularly clean the lens with a cotton swab dipped in alcohol and follow the instruction label on the scanner. Only use gentle pressure for cleaning to avoid lens damage. Do not use bleach or other cleaning solutions on the sensor lens.



Cleaning the Exergen probe head and neck

Use an alcohol-based cleaning agent on the Exergen scanner's probe head and metal neck only.

Cleaning and disinfecting blood pressure cuffs and air hoses

General

Before reuse, the cuff and the air hose must be thoroughly cleaned with a cleaning agent listed in "List of approved cleaning agents" on page B-4.

WARNINGS

Consult the manufacturer for specific cleaning or disinfection instructions of the cuffs and air hoses. The user has the responsibility to validate any deviations from the recommended method of cleaning and disinfection.

Never autoclave or steam clean the monitor, cuffs, or accessories.

Cleaning the Welch Allyn probe and probe well

Units that are in service on a regular basis should have the following preventive maintenance performed every six months:

1. Visually inspect the thermometer probe for any physical damage that might cause future product failure.
2. Clean the probe and the probe well according to instructions below. Use an alcohol-based cleaning agent on the Welch Allyn metal probe or plastic section of the probe only.

Cleaning the Welch Allyn probe

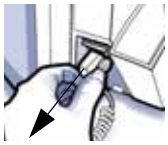
As needed, clean the probe with a 70% isopropyl alcohol solution or a 10% chlorine bleach solution or a nonstaining disinfectant such as CaviCide® or its equivalent.

WARNING
Do not immerse or soak the probe in any type of fluid. ***Do not*** use steam, heat or gas sterilization on the probe. ***Do not*** autoclave the probe.

CAUTION
Never immerse any monitor accessories.

Cleaning the removable probe well

1. Remove the probe well from the unit.
2. Unplug the latching probe connector to prevent the monitor from consuming battery power while you are cleaning the probe well.



3. Clean the inner surface of the probe well by swabbing the surface with a cloth dampened with a mild detergent solution or a 70% isopropyl alcohol, or a 10% chlorine bleach solution, or a nonstaining disinfectant such as CaviCide® or its equivalent.
4. Clean the probe well's outer surface by swabbing or wiping the surface with one of the solutions mentioned above. Immerse the probe well in mild detergent solution as necessary for cleaning.
5. Thoroughly dry all surfaces before re-assembling the instrument.
6. Reconnect the latching probe connector to the monitor. Ensure that the connector snaps into place.
7. Reinstall the probe well in the monitor and snap the probe well into place.
8. Insert the probe into the probe well.

WARNING

Do not use hard or sharp objects to clean the probe well. This could damage it and cause the unit to not function properly. *Do not* use steam, heat or gas sterilization on the thermometer or probe. *Do not* autoclave the probe well.

9. Periodically clean the probe's surface by wiping it with a soft cloth, sponge or soft brush dampened with a cleaning agent listed above for Welch Allyn. Then wipe dry with a clean cloth or towel.

Cleaning SpO_2 sensors

Adhesive sensors are sterile and for single use only. For reusable SpO_2 sensors, consult the sensor manufacturer instructions for cleaning, sterilization, or disinfecting methods.

Battery and monitor storage care

Short-term storage

The monitor and its accessories should be stored in a clean and stable place with no weight applied on them.

Keep the monitor connected to an external DC power source when not in use to ensure maximum battery charge. As long as the monitor remains connected to an external DC power source, the monitor will charge the battery whenever software determines it necessary.

Batteries should always be connected and fully charged before being placed in short-term storage. It is recommended that batteries should not be left in storage more than 2 weeks without a full recharge. When the battery will no longer hold a charge, contact service for battery replacement.

NOTE

After replacing batteries/battery discharge/patient discharge, the monitor will clear user settings and revert to default settings set in the configuration mode.

Extended storage

When storing the monitor for extended periods, contact service for battery disconnection and packing of the monitor and the accessories.

Storage temperature

When packaged according to instructions in the Service Manual, the device survives a storage temperature range of – 20° C to + 50° C (– 4° F to + 122° F).

Repairs

If your product requires warranty, extended warranty, or non-warranty repair service, contact Innokas Medical Technical Support or your local Innokas Medical representative.

Estimates for non-warranty repairs are provided at no charge; however, the product must be sent to Innokas Medical for an estimate. To facilitate prompt service in cases where the product has external chassis or case damage, please advise the representative when you call.

The representative will record all necessary information and will provide a Return Authorization Number. Prior to returning any product for repair, a Return Authorization Number must be obtained.

Changing the Exergen temperature unit battery

Required tools and parts

- Paper clip or metal pin of equal thickness
- A new quality alkaline 9V battery

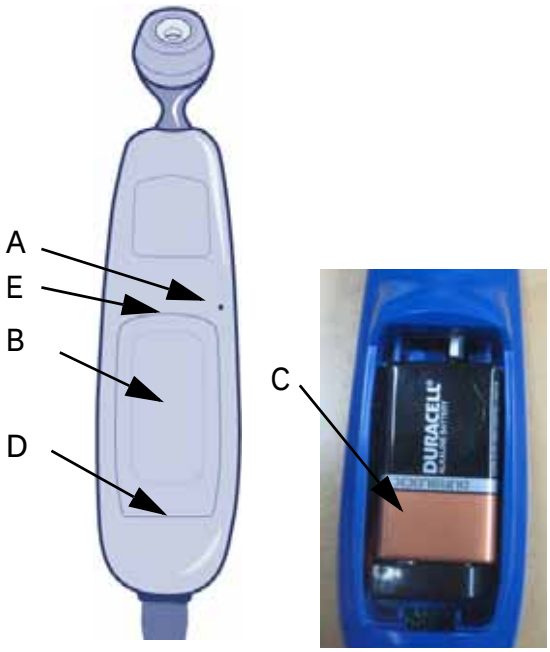
NOTE

If the Exergen scanner is not used regularly, remove the battery to prevent possible damage due to chemical leakage.

Procedure

1. Unplug the scanner cable from the monitor USB port.
2. Bend a paper clip or obtain a metal pin of equal thickness and then insert it into a small hole on the side of the Exergen frame (A).
3. Push the pin inside until the battery cover (B) is released.
4. Remove the cover.
5. Remove and disconnect the battery (C).
6. Replace the battery.
7. Place the lower end of the cover (D) in the groove.
8. Then push the upper part (E) down until it locks up.

9. Plug the scanner cable into the USB port.



Verification

Check the LED display. The low battery error message should not be displayed. Perform a temperature measurement to determine whether the Exergen unit is powered correctly. Refer to "Disposal of product waste" on page B-11 for battery disposal instructions.

Packaging material

Retain original packaging materials for future use in storing or shipping the monitor and accessories. This recommendation includes corrugated shippers and foam/corrugated spacers.

If you decide to dispose of these materials, we recommend recycling them.

Packing instructions

If you have to return goods for service, follow these instructions:

- Remove all hoses, cables, sensors, and power cords from the monitor before packing.
- Clean the unit as instructed in "Cleaning" on page B-4.
- Ask service to pack the unit for shipping.

Disposal of product waste

As you use the monitor, you will accumulate solid wastes that require proper disposal or recycling. These include batteries, patient applied parts, and packaging material. Dispose of these materials according to local or national regulations.

Batteries

The Li-Ion rechargeable battery can be recycled. Do not puncture or place the battery in a trash compactor. Do not incinerate the battery or expose it to fire or high temperatures. Dispose of these materials according to local or national regulations.

Dispose any battery in accordance with local regulations on material recycle.

Patient-applied parts

Certain patient-applied parts, such as those with adhesive (disposable SpO_2 sensors), are intended for single use and should be disposed of properly as medical waste in accordance with regional body controlled guidelines.

Other patient-applied parts, such as blood pressure cuffs, should be cleaned according to instructions. Inspect reusable applied parts for wear before each use, replace as necessary, and dispose of used product as medical waste in accordance with regional body controlled guidelines.

Monitor

At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, please contact Innokas Medical or its representatives.

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C Principles of noninvasive blood pressure determination (NIBP)

DINAMAP SuperSTAT algorithm

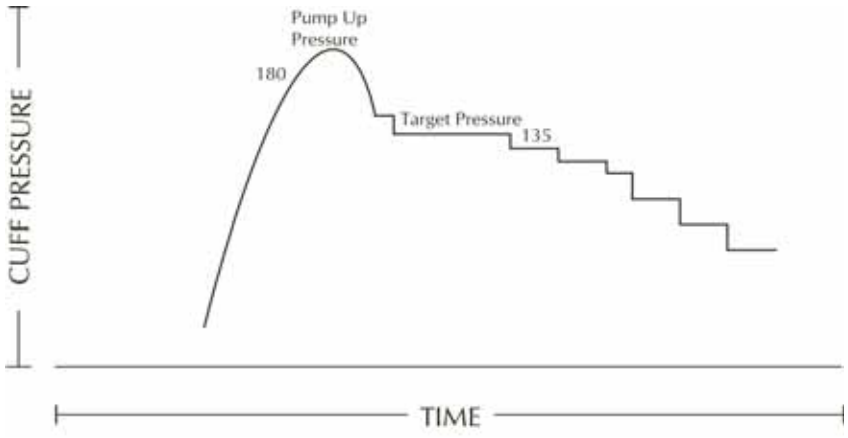
The oscillometric method of determining NIBP is accomplished by a sensitive transducer which measures cuff pressure and pressure oscillations within the cuff. For the first determination taken on a patient, the algorithm stores the pattern of the patient's oscillation size as a function of the pressure steps.

When NIBP measurements are performed: 1) the monitor will use a previous NIBP value for adaptive target inflation pressure as long as this is displayed on the screen. 2) the NIBP values are displayed for a maximum of 30 minutes or until another determination is initiated. When the values on the screen expire or the patient is discharged, the adaptive target pressure will be automatically cleared.

For subsequent single, auto, or STAT determinations taken before data of the previous determination of the same patient has expired, as few as four pressure steps may be necessary to complete the determination process. When employing fewer pressure steps, the system uses the stored information from the previous blood pressure determination to decide the best pressure steps to take. The algorithm measures the consistency of pulse size to tell if the oscillations taken at a step are good and if more steps are needed.

The first determination settles at an initial target pressure of 135 mmHg (adult mode) and 100 mmHg (neonate mode), depending on initial target pressure preset. To allow for rapid settling of cuff pressure, the monitor will momentarily inflate to a higher pressure then immediately deflate to the target pressure. After inflating the cuff, the NIBP parameter begins to deflate. The oscillations versus cuff pressure are measured to determine the mean pressure and calculate the systolic and diastolic pressures.

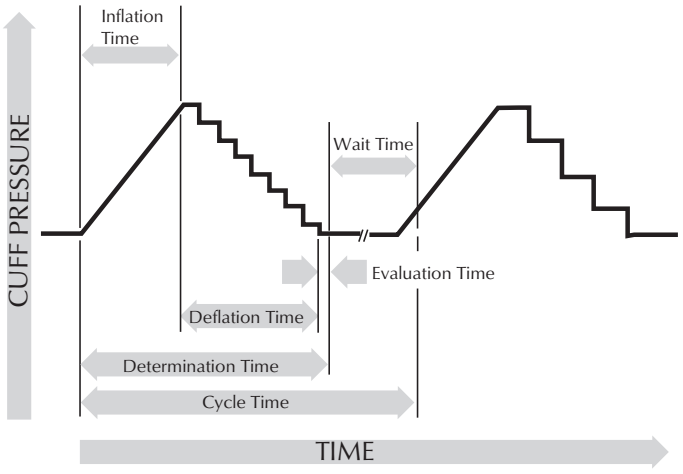
During an NIBP determination, the parameter deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. The time between deflation steps depends on the frequency of these matched pulses (pulse rate of the patient). However, if the monitor is unable to find any pulse within several seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances the accuracy of the monitor. The figure shows a full determination sequence for an adult patient.



Full NIBP determination sequence for adult
(specific pressure values are examples only)

At each step the microprocessor stores cuff pressure, the matched pulse amplitude, and the time between successive pulses. The stepped deflation and matched pulse detection continues until diastolic pressure is determined or total cuff pressure falls below 8 mmHg. The parameter then deflates the cuff (to zero detected pressure), analyzes the stored data, and updates the screen.

The operating cycle is composed of four parts: inflation time, deflation time, evaluation time, and wait time. Wait time, which varies from mode to mode, is affected by the cycle time (auto mode) or operator intervention (manual mode). The figure shows the basic operating cycle for an NIBP determination.



SuperSTAT NIBP - auto mode

Systolic search

NOTE

Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure.

If systolic pressure is not found, the SuperSTAT algorithm can search at cuff pressures higher than the initial target pressure. The algorithm will inflate above the initial target pressure to obtain more data in the systolic region. The pressure is limited to the maximum allowed for the selected patient type.

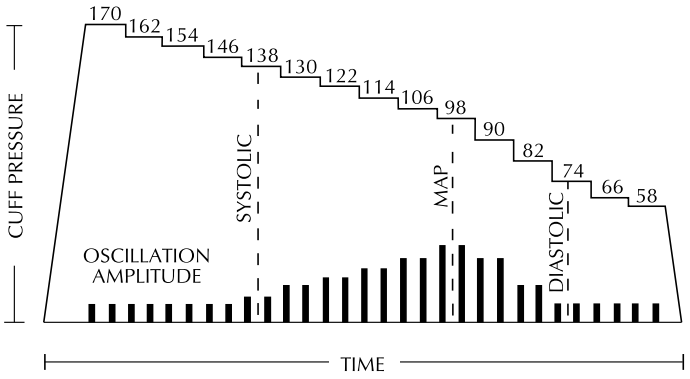
The SuperSTAT algorithm evaluates the data obtained during the determination, and the prior determination if it is available, to determine if additional data is needed to complete the determination. It can then selectively pump to a single cuff pressure to obtain the data it needs and then return to the existing deflation sequence. This search process makes SuperSTAT more efficient.

Accuracy of the SuperSTAT NIBP measurements was validated against the intra-arterial method. Do not use the auscultatory method to verify the accuracy of the SuperSTAT NIBP parameter. The auscultatory method (using the cuff and stethoscope) determines the systolic and diastolic pressures from sounds that occur during cuff deflation. Mean arterial pressure cannot be determined by the auscultation method. The oscillometric method used with all DINAMAP technologies determines systolic, mean and diastolic pressures from the oscillation pattern that occurs in the cuff during deflation.

DINAMAP auscultatory reference algorithm

The oscillometric method of determining NIBP is accomplished by a sensitive transducer, which measures cuff pressure and minute pressure oscillations within the cuff. The first determination sequence initially pumps up to a cuff pressure of about 160 mmHg for adult/pediatric patients depending on preset initial target pressure. After inflating the cuff, the monitor begins to deflate it and measures systolic pressure, mean arterial pressure, and diastolic pressure. When the diastolic pressure has been determined, the monitor finishes deflating the cuff and updates the screen.

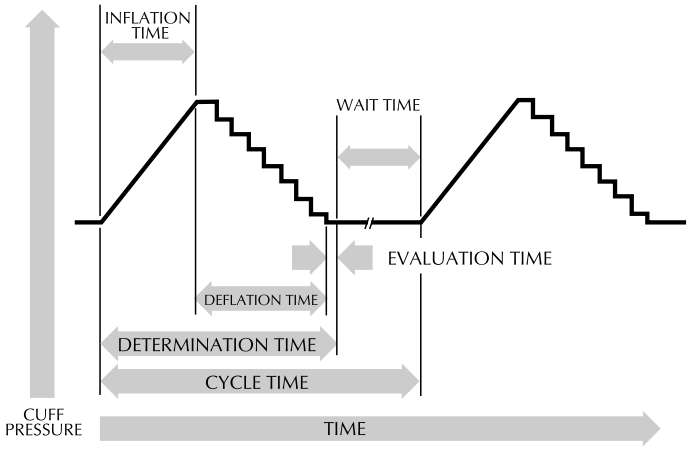
The auscultatory reference is an algorithm based upon Korotkoff sounds and a stethoscope. It is used only for adults/peds because neonates and babies/ toddlers under 3 years do not produce adequate Korotkoff sounds. The monitor deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. The time between deflation steps depends on the frequency of these matched pulses (pulse rate of the patient). However, if the monitor is unable to find any pulse within several seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances the accuracy of the monitor. The figure shows the NIBP determination sequence.



NIBP determination sequence
(specific pressure values are examples only)

At each step the microprocessor stores cuff pressure, the matched pulse amplitude, and the time between successive pulses. The stepped deflation and matched pulse detection continues until diastolic pressure is determined or total cuff pressure falls below 7 mmHg. The monitor then deflates the cuff (to zero detected pressure), analyzes the stored data, and updates the screen.

The operating cycle is composed of four parts: inflation time, deflation time, evaluation time, and wait time. Wait time, which varies from mode to mode, is affected by the cycle time (auto mode) or operator intervention (manual mode). The figure shows the basic operating cycle.



NIBP operating cycle

Systolic search

If systolic pressure is not found, the NIBP parameter can search at cuff pressures higher than the initial target pressure. The parameter will inflate the cuff above the initial target pressure to get more data in the systolic region. The pressure is limited to the maximum allowed for the selected patient type.

In any operating mode, if a patient's systolic pressure exceeds the inflation pressure of the monitor, the monitor will begin normal deflation sequence, detect the absence of a systolic value, stop deflation, reinflate to a higher (than initial) inflation pressure, and resume normal deflation sequence.

In manual mode, if a previous valid systolic pressure is displayed and less than 2 minutes old, and the new systolic pressure oscillations are compared with the previous valid determination and the monitor "thinks" that the systolic was not obtained, the monitor will inflate the cuff to a pressure above the immediately preceding inflation.

Reference used to determine NIBP accuracy

To establish accuracy of an NIBP device, manufacturers have used several different types of references. The reference blood pressures may be obtained by invasive pressure monitoring at the central aortic region or at the radial sites. The reference blood pressures may also be obtained by noninvasive methods like auscultatory method (using cuff and stethoscope).

NOTE

For neonatal mode, the reference is always the intra-arterial pressure monitoring method.

Monitors with intra-arterial reference (DINAMAP SuperSTAT technology)

In these monitors, the NIBP is referenced to the invasive blood pressure obtained at the central aortic region.

Monitors with auscultatory reference (DINAMAP auscultatory reference technology)

In these monitors, the reference blood pressure is the auscultatory method for adult and pediatric populations. For neonatal populations, the usual reference is the invasive blood pressure obtained from the umbilical artery.

NOTE

For neonatal determinations the SuperSTAT algorithm is always used.

D Supplemental analysis of clinical accuracy test data

GE TruSignal V2

Supplemental Analysis of Clinical Accuracy Test Data for GE TruSignal V2 SpO_2 Measurement

The supplemental data analysis is performed to present the data per a format of Bland-Altman[1].

The supplemental analysis includes the Bland-Altman graph with a linear regression fit and the upper 95% and lower 95% limits of agreement (Mean ± 1.96 * standard deviation). Additionally the sampled data points are differentiated for each individual test subject by color and style. Figures 1 to 8 represent different sensors under test.

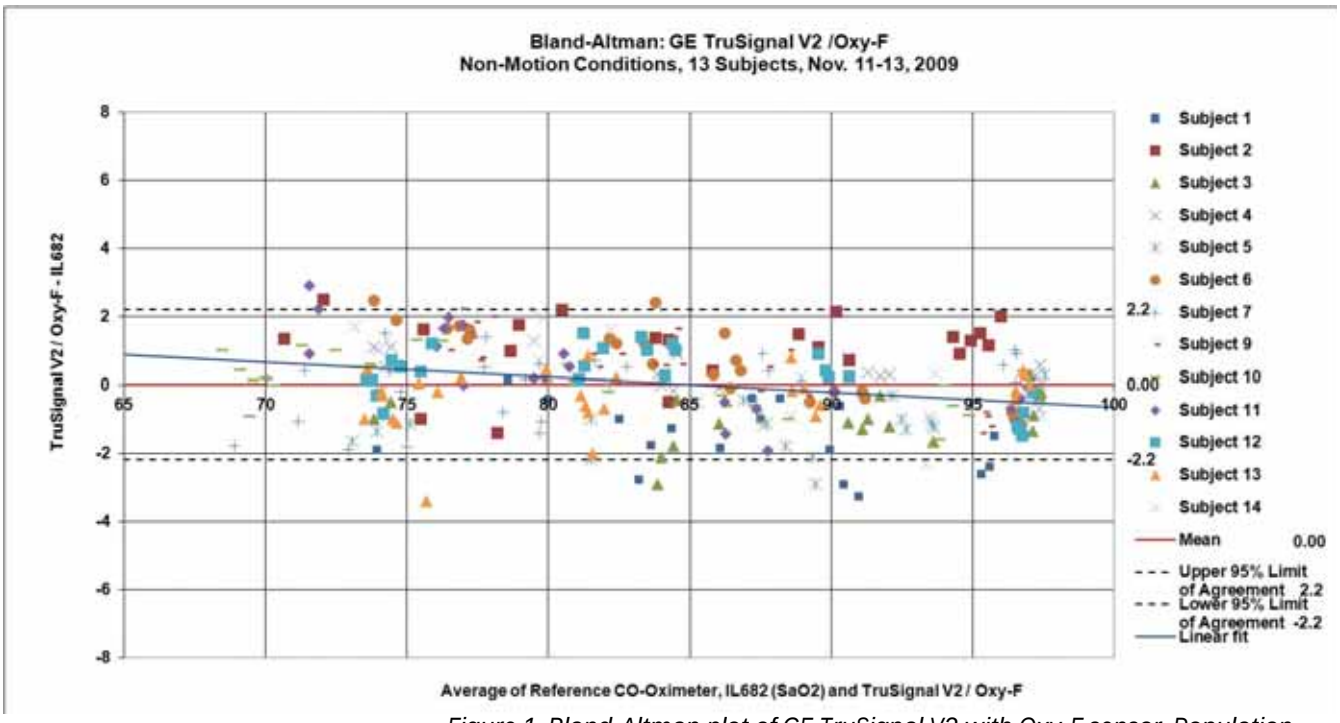


Figure 1. Bland-Altman plot of GE TruSignal V2 with Oxy-F sensor. Population mean bias: 0.0, upper 95% limit of agreement: 2.2, lower 95% limit of agreement: -2.2, between subject variance: 10.2, within-subject variance: 0.9.

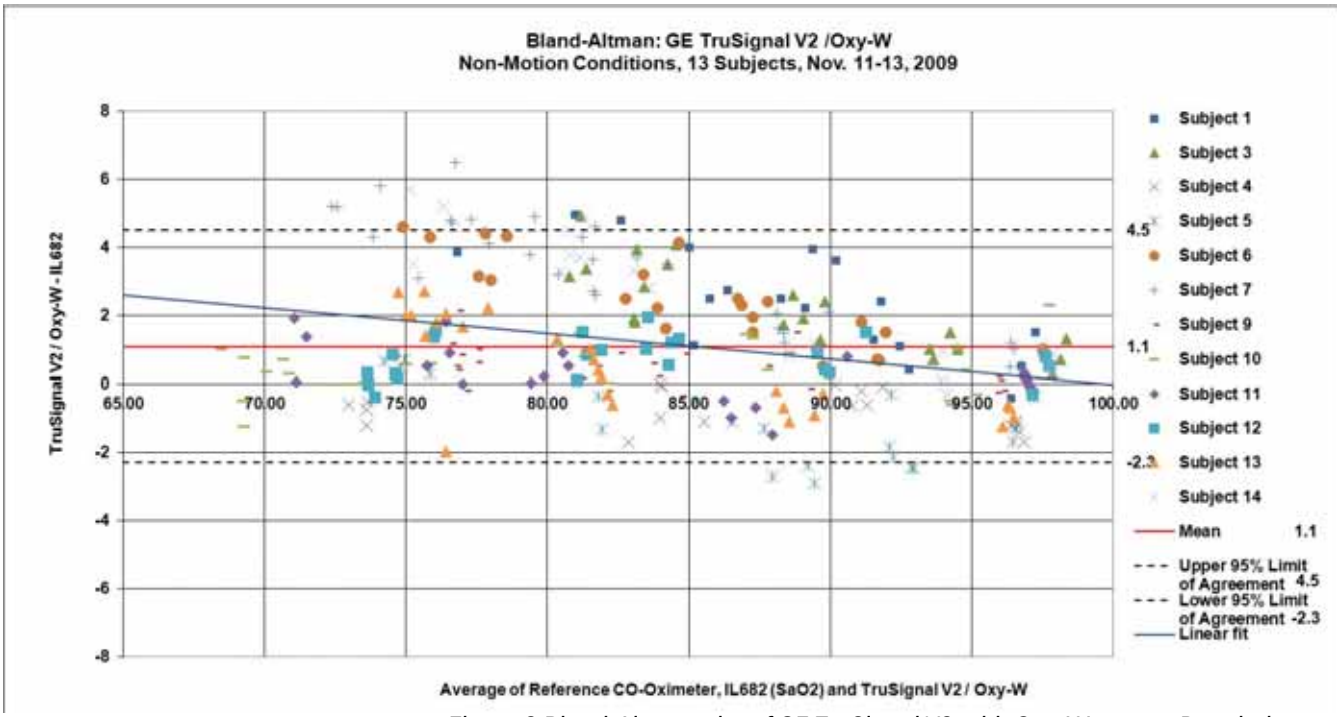


Figure 2 Bland-Altman plot of GE TruSignal V2 with Oxy-W sensor. Population mean bias: 1.1, upper 95% limit of agreement: 4.5, lower 95% limit of agreement: -2.3, between subject variance: 41.5, within-subject variance: 1.5.

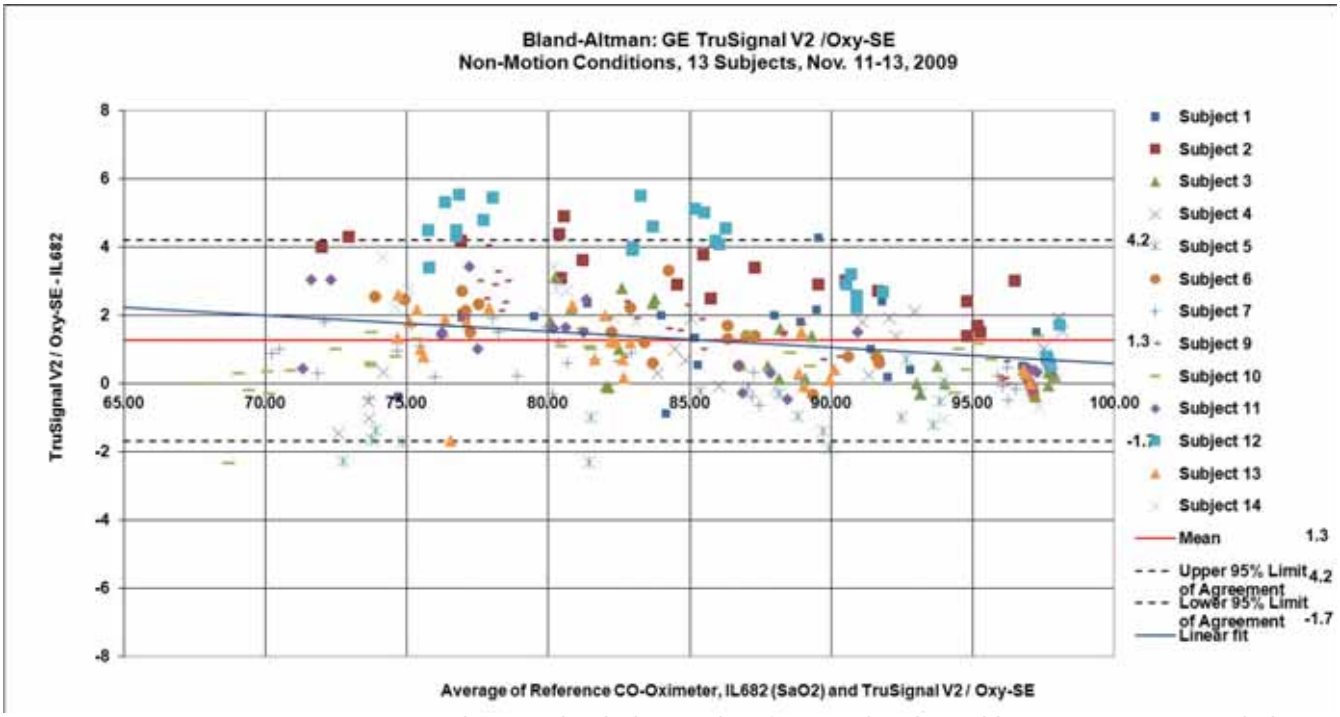


Figure 3 Bland-Altman plot of GE TruSignal V2 with Oxy-SE sensor. Population mean bias: 1.3, upper 95% limit of agreement: 4.2, lower 95% limit of agreement: -1.7, between subject variance: 29.2, within-subject variance: 1.2.

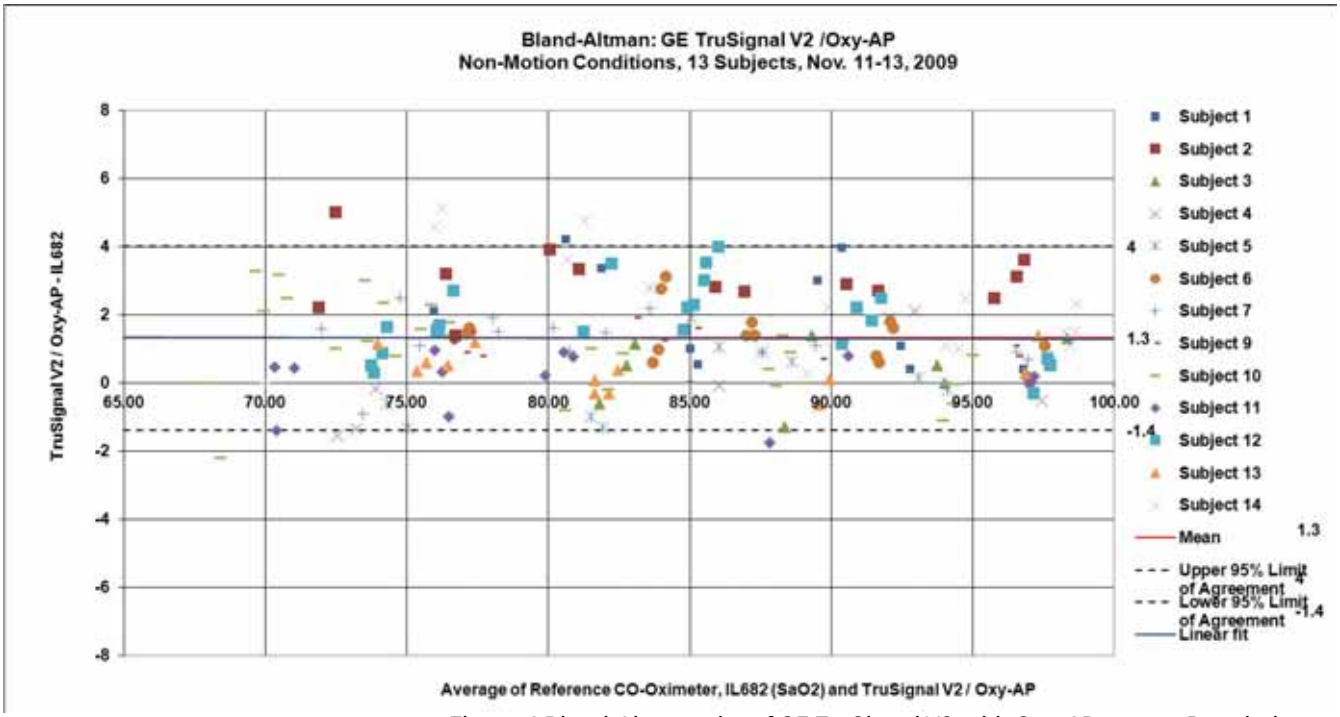


Figure 4 Bland-Altman plot of GE TruSignal V2 with Oxy-AP sensor. Population mean bias: 1.3. Upper 95% limit of agreement: 4.0, lower 95% limit of agreement: -1.4. Between subject variance: 11.4, within-subject variance: 1.3.

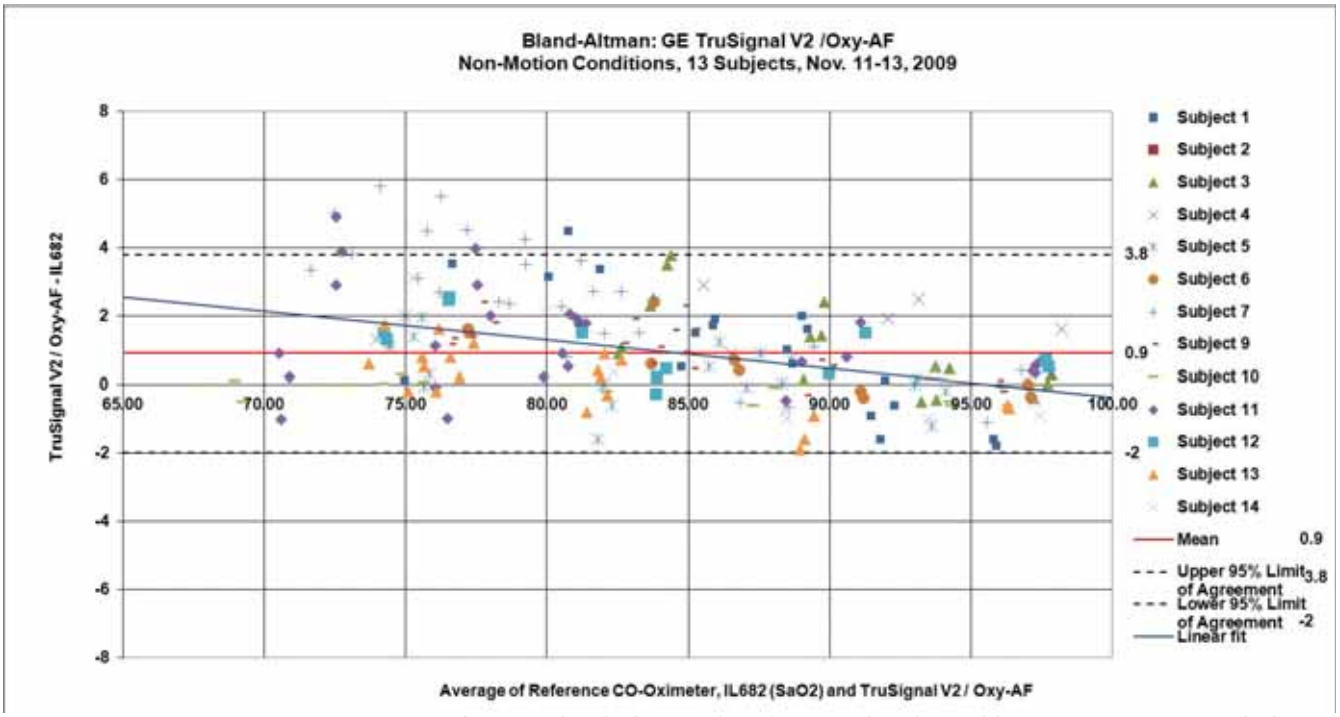


Figure 5 Bland-Altman plot of GE TruSignal V2 with Oxy-AF sensor. Population mean bias: 0.9, upper 95% limit of agreement: 3.8, lower 95% limit of agreement: -2.0, between subject variance: 10.7, within-subject variance: 1.7.

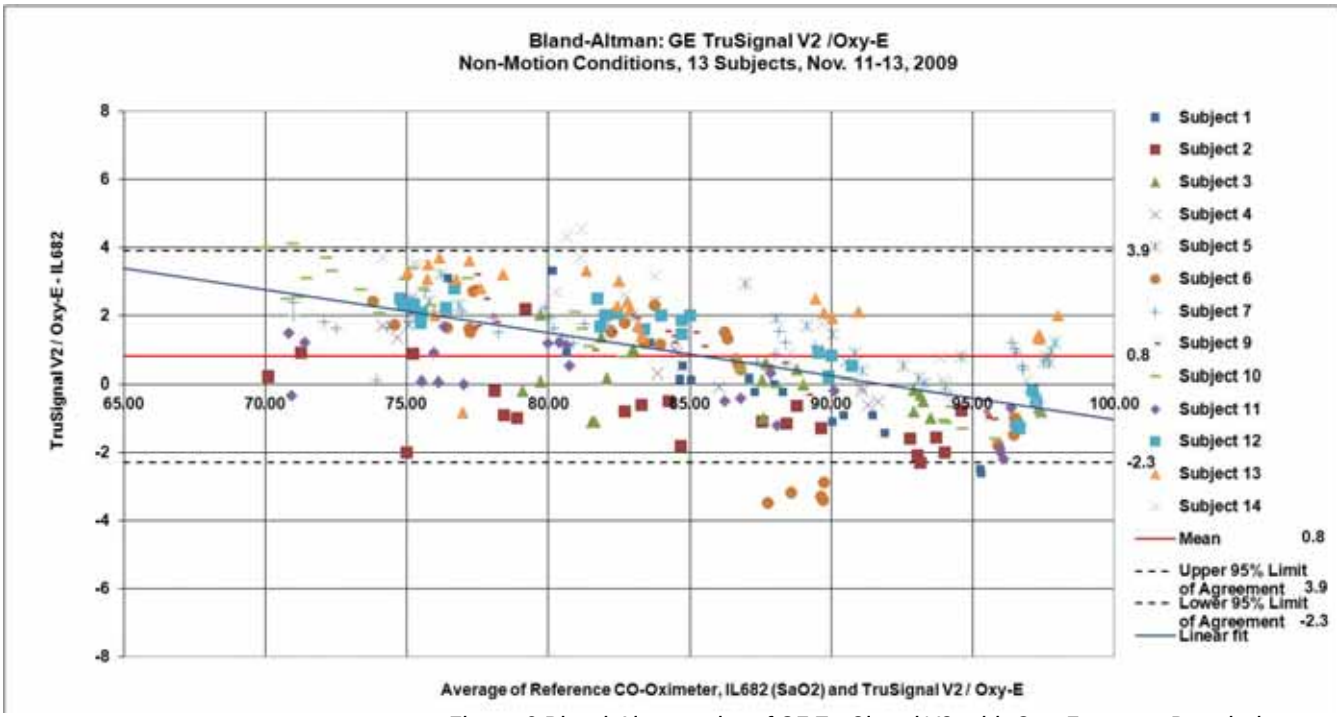


Figure 6 Bland-Altman plot of GE TruSignal V2 with Oxy-E sensor. Population mean bias: 0.8, upper 95% limit of agreement: 3.9, lower 95% limit of agreement: -2.3, between subject variance: 20.8, within-subject variance: 1.7.

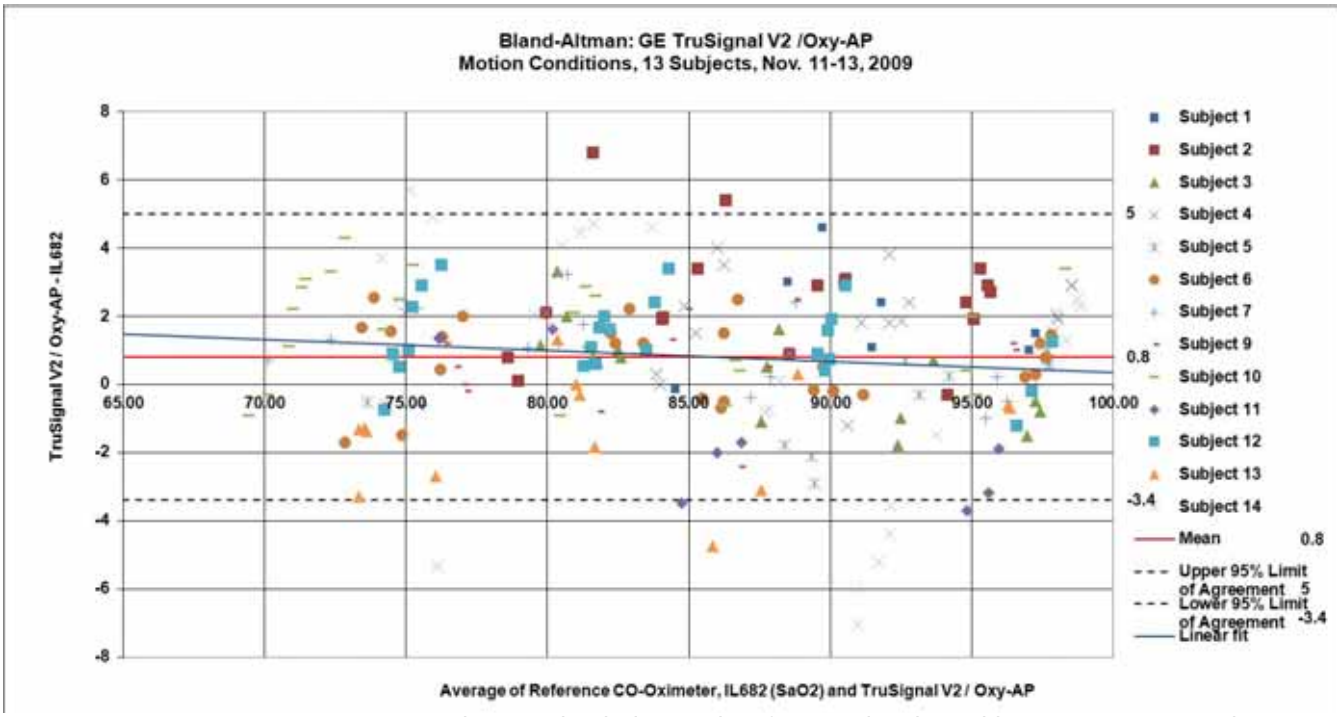


Figure 7 Bland-Altman plot of GE TruSignal V2 with Oxy-AP sensor, motion conditions. Population mean bias: 0.8. Upper 95% limit of agreement: 5.0, lower 95% limit of agreement:-3.4. Between subject variance: 22.6, within-subject variance: 3.6.

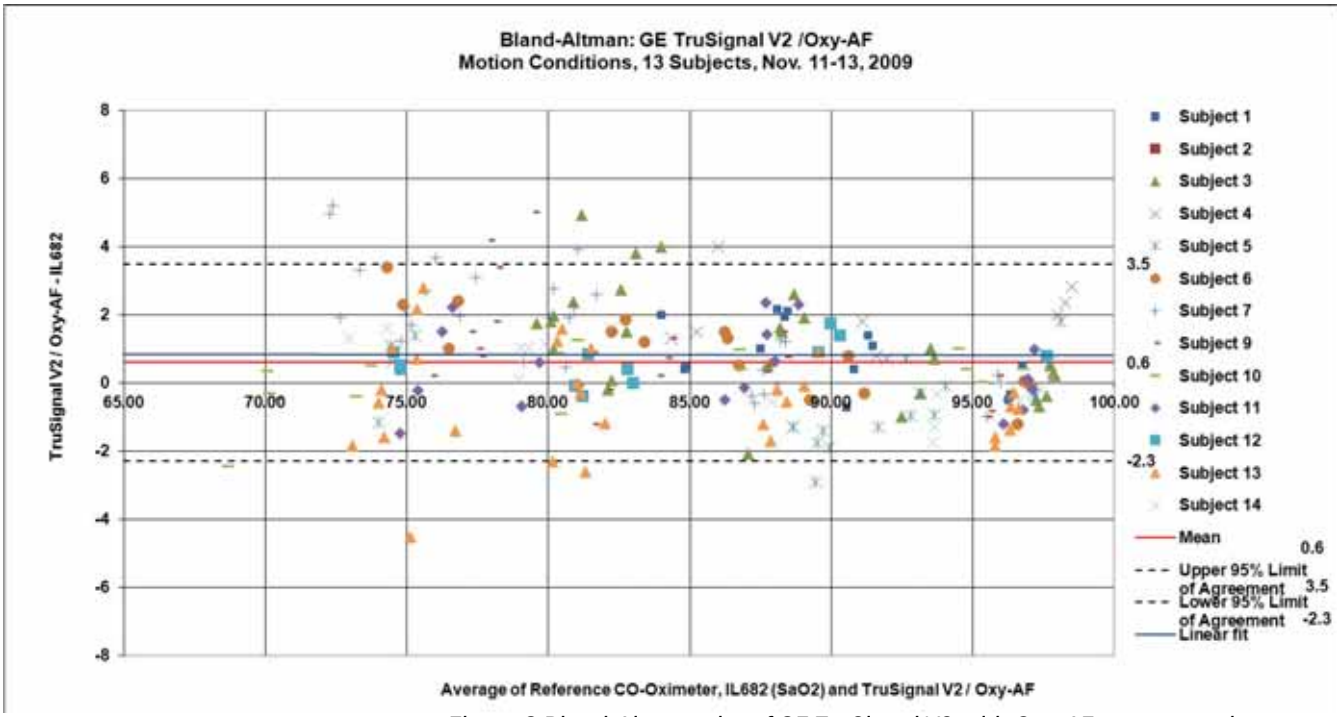


Figure 8 Bland-Altman plot of GE TruSignal V2 with Oxy-AF sensor, motion conditions. Population mean bias: 0.6. Upper 95% limit of agreement: 3.5, lower 95% limit of agreement:-2.3. Between subject variance: 10.5, within-subject variance: 1.7.

Reference:

[1] *"Agreement Between Methods Of Measurement With Multiple Observations Per Individual", by Bland and Altman in 2007 Journal of Biopharmaceutical Statistics. Section 3: Method Where the True Value Varies.*

Clinical test results

Arms values measured using GE SpO_2 sensors with GE CARESCAPE™ V100 in a clinical study.*			
GE SpO_2 Sensor	70 - 80%	80 - 90%	90 - 100%
*The sensors were clinically tested for accuracy with the following sensors:			
OXY-E	2.3 digits	1.4 digits	1.3 digits
OXY-SE	2.5 digits	2.0 digits	1.1 digits
OXY-F	1.3 digits	1.0 digits	1.1 digits

OXY-W	2.9 digits	1.8 digits	1.0 digits
OXY-AP	2.0 digits	1.9 digits	1.7 digits
OXY-AF	2.5 digits	1.4 digits	0.9 digits

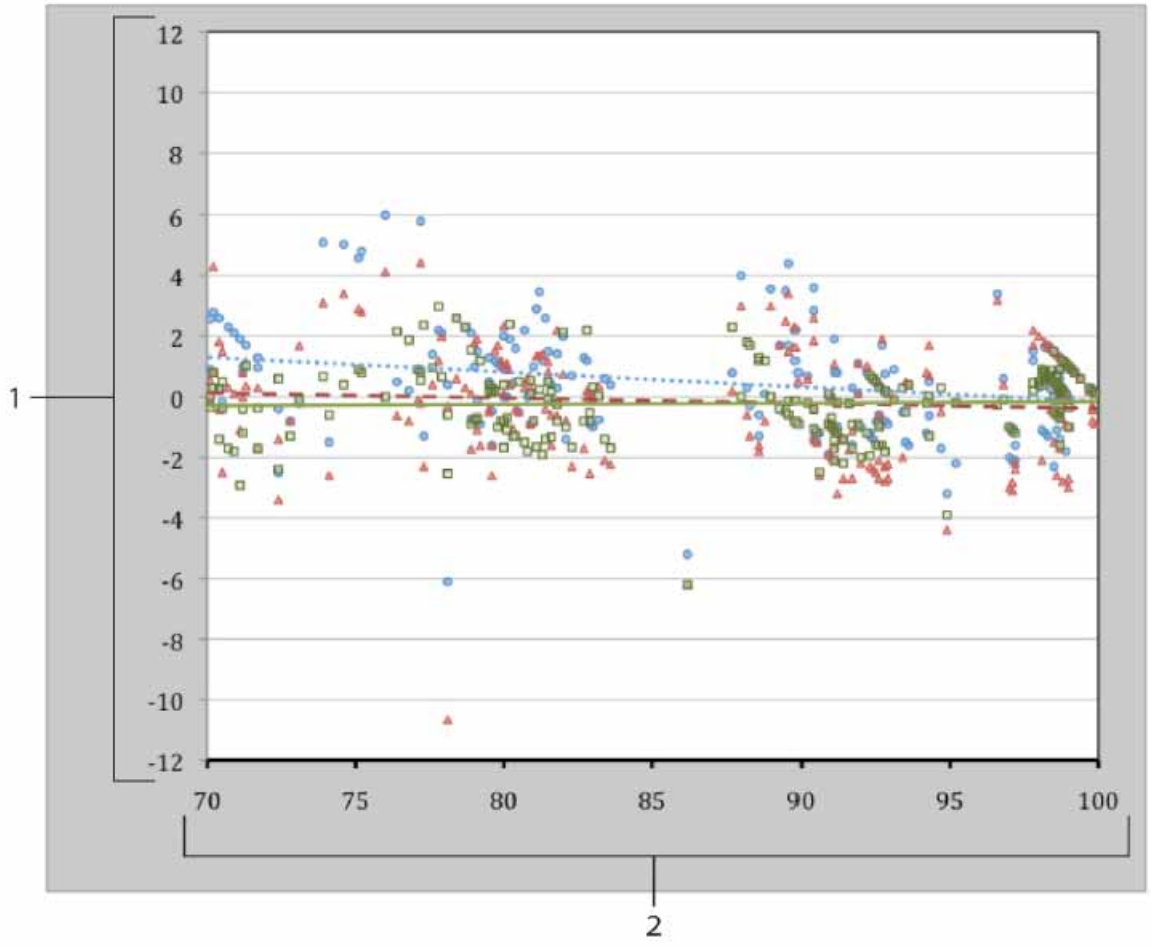
*The sensors were clinically tested for accuracy with the following sensors:
OXY-E (equivalent to OXY-E-UN, TS-E-D, TS-E2-GE, TS-E4-GE)
OXY-SE (equivalent to OXY-SE-3, TS-SE-3)
OXY-F (equivalent to OXY-F-UN, TS-F-D, TS-F2-GE, TS-F4-GE, TS-SA-D, TS-SA4-GE)
OXY-W (equivalent to OXY-W-UN, TS-W-D)
OXY-AP (equivalent to OXY-AP-10, OXY-AP-25, TS-AP-10, TS-AP-25)
OXY-AF (equivalent to OXY-AF-10, TS-AF-10, TS-AF-25)

*The sensors were clinically tested for neonatal accuracy with the following sensors:
OXY-SE (equivalent to OXY-SE-3, TS-SE-3)
OXY-AF (equivalent to OXY-AF-10, TS-AF-10, TS-AF-25)

Nellcor accuracy study results

Accuracy was calculated using the root mean square difference (RMSD).

SpO_2 Accuracy for Nellcor™ Sensors vs. CO-oximeters						
SpO_2 decade	MAX-A		MAX-N		MAX-FAST	
	Data Points	Arms	Data Points	Arms	Data Points	Arms
60-70	71	3.05	71	2.89	71	2.22
70-80	55	2.35	55	2.32	55	1.28
80-90	48	1.84	48	1.73	48	1.48
90-100	117	1.23	117	1.68	117	0.98



Modified Bland-Altman plot

1	Test Sensor; Avg CO-oximeter value 70-100% SpO2	2	71
	Oximetry board with MAX-A sensor		Trendline of MAX-A sensor
	Oximetry board with MAX-N sensor		Trendline of MAX-N sensor
	Oximetry board with MAX-FAST sensor		Trendline of MAX-FAST sensor

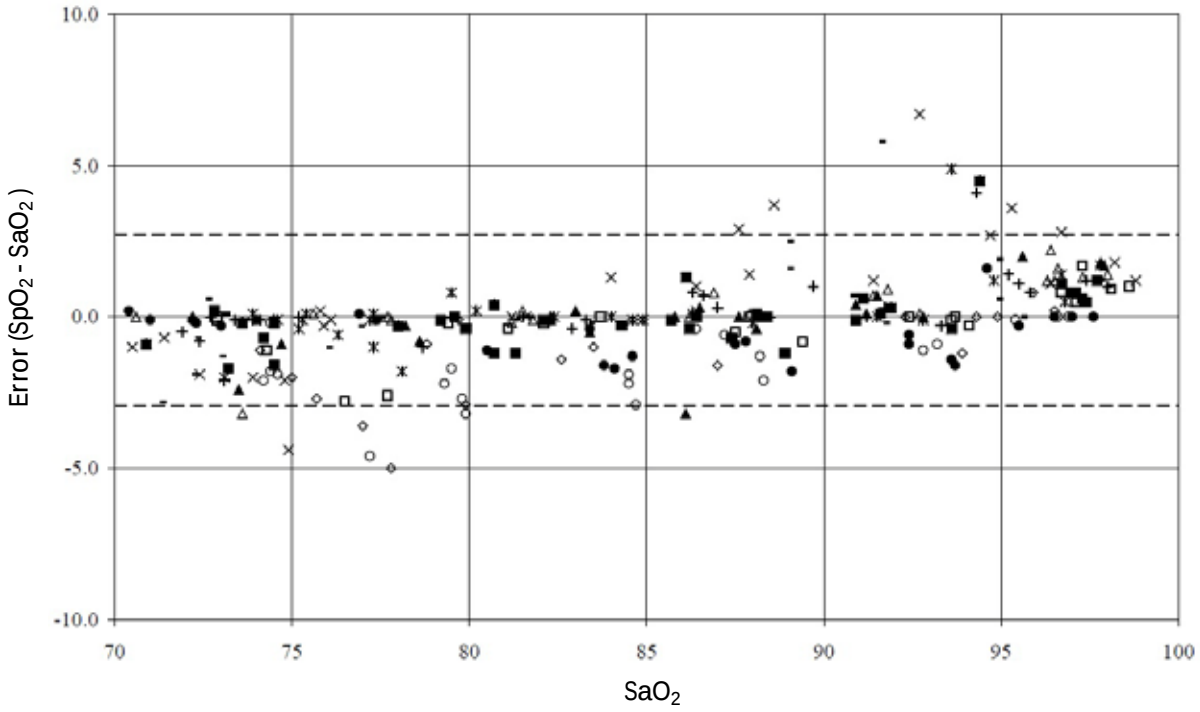
Masimo sensor accuracy

Performance Specifications for Masimo M-LNCS, LNCS, and LNOP Adhesive Sensors

Table information provides Arms values measured using the M-LNCS Series, LNCS Series and LNOP Series sensors with Masimo SET Oximetry Technology in a clinical study. SaO_2 versus error (SpO_2 – SaO_2) with linear regression fit and upper 95% and lower 95% limits of agreement.

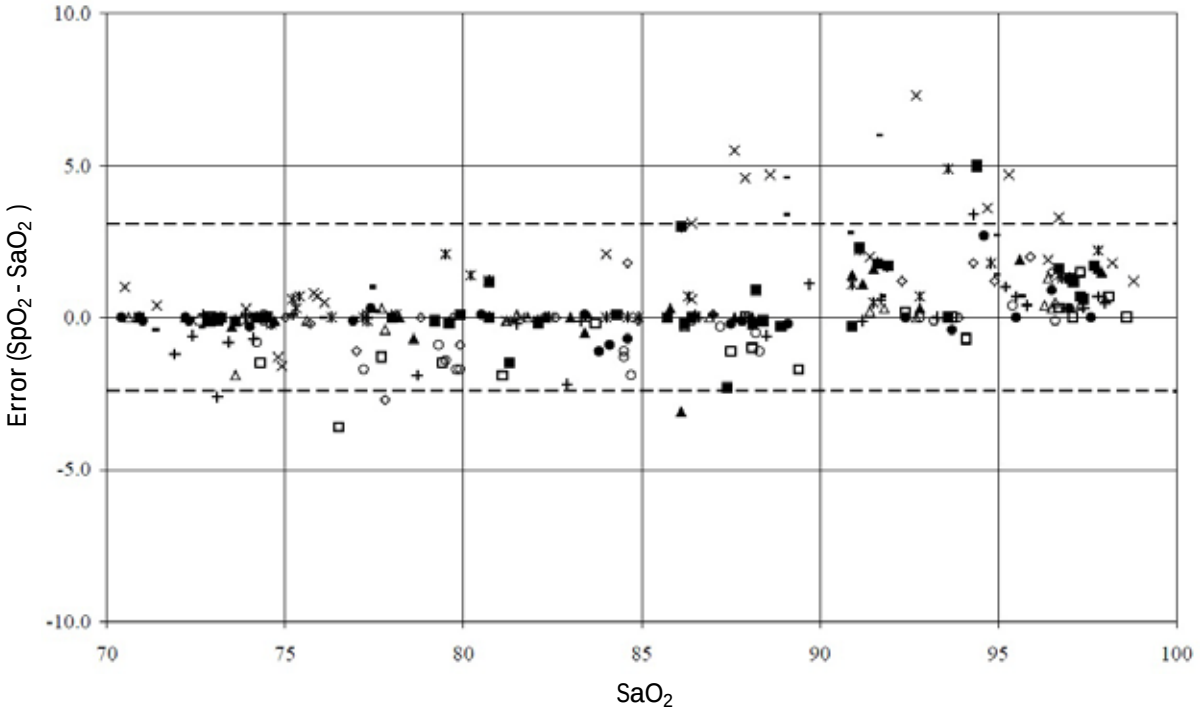
M-LNCS/LNCS/LNOP - Adtx/Pdtx

M-LNCS/LNCS/LNOP - Adtx/Pdtx, measured values	
Range	Arms
90-100%	1.64%
80-90%	1.07%
70-80%	1.55%
Overall Claimed Accuracy Value	
70-100%	± 2%



M-LNCS/LNCS/LNOP - Inf/Neo/NeoPt

M-LNCS/LNCS/LNOP - Inf/Neo/NeoPt, measured values			
Range	Arms		
90-100%	1.85%		
80-90%	1.44%		
70-80%	0.89%		
Overall Claimed Accuracy Value			
Range	Arms		
	Inf	Neo*	Neo Pt*
70-100%	± 2%	± 2% Adult ± 3% Neonatal	± 3%
*The saturation accuracy of the Neonate and Preterm sensors was validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.			

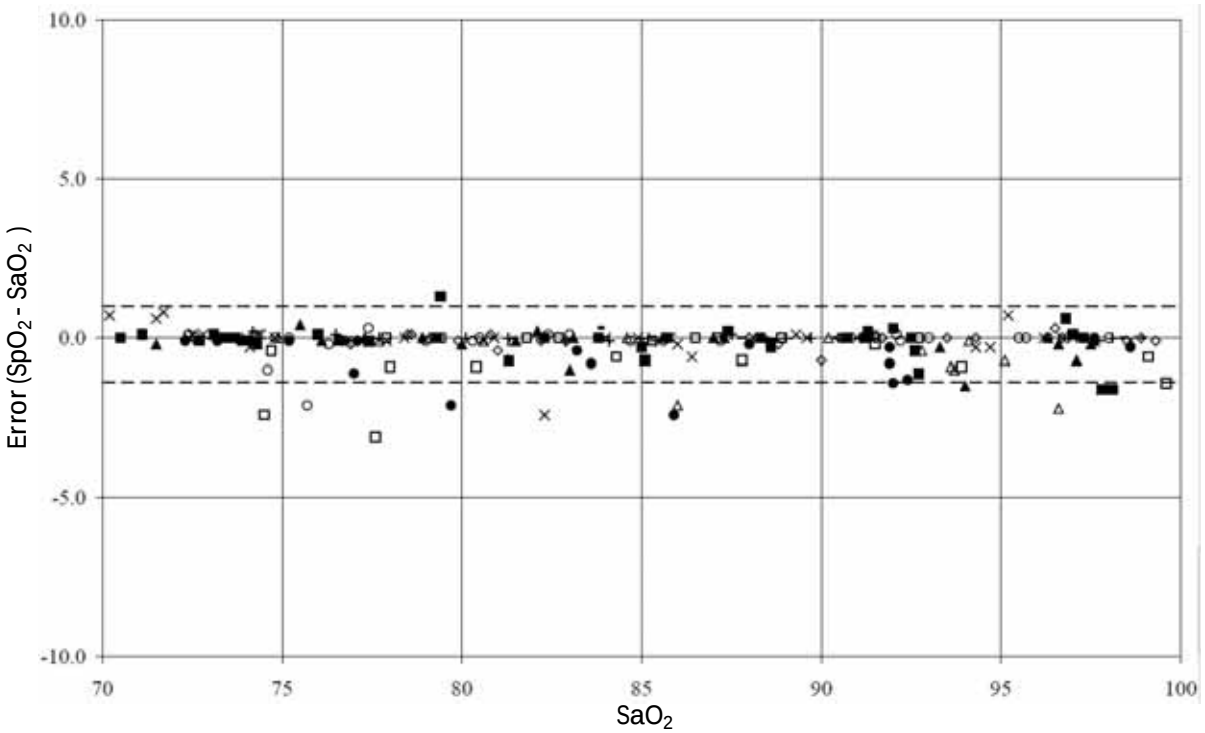


M-LNCS/LNCS/LNOP DCI and DCIP

Table information provides Arms values measured using the M-LNCS/LNCS/ LNOP DCI and DCIP sensors with Masimo SET Oximetry Technology in a clinical study.

SaO_2 versus error (SpO_2 - SaO_2) with linear regression fit and upper 95% and lower 95% limits of agreement.

M-LNCS/LNCS/LNOP - DCI and DCIP, measured values	
Range	Arms
90-100%	0.6%
80-90%	0.5%
70-80%	0.7%
Overall Claimed Accuracy Value	
70-100%	± 2%

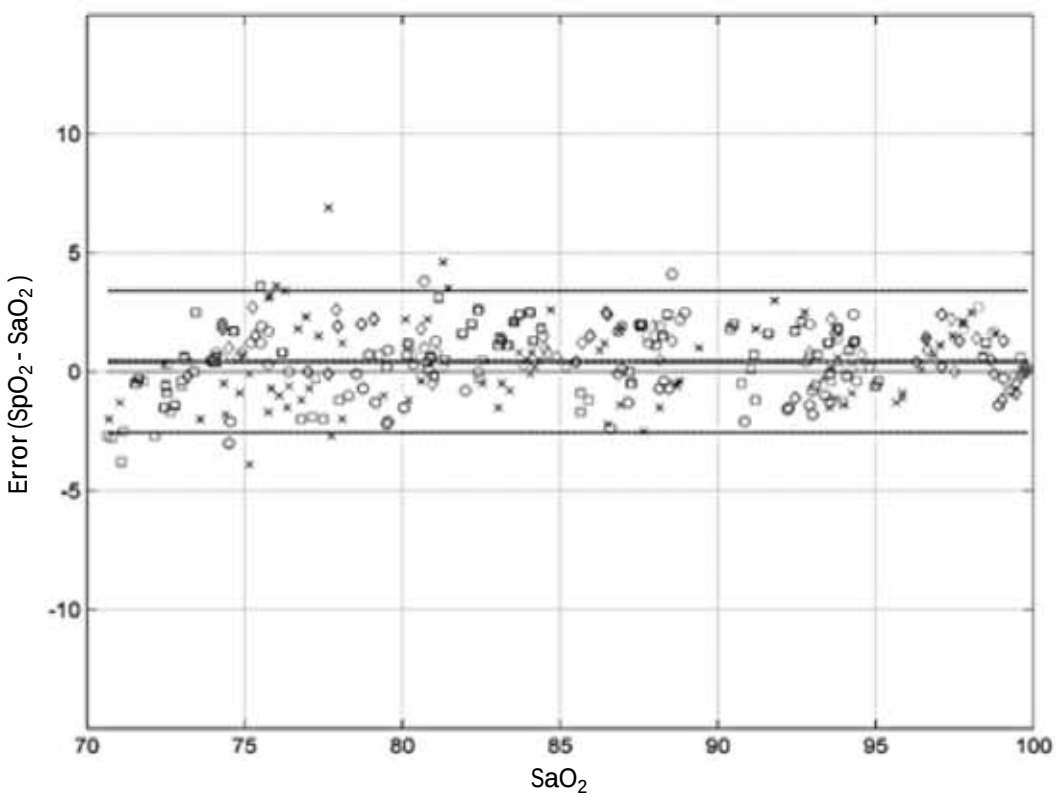


Performance specifications for Rainbow ReSposable Pulse CO-Oximeter Sensor System

Rainbow Adhesive and Resposable Sensors

The table below shows Arms (Accuracy Root Mean Square) values measured using the Rainbow Adhesive and Resposable Sensors sensors with Masimo SET Oximetry Technology in a clinical study.

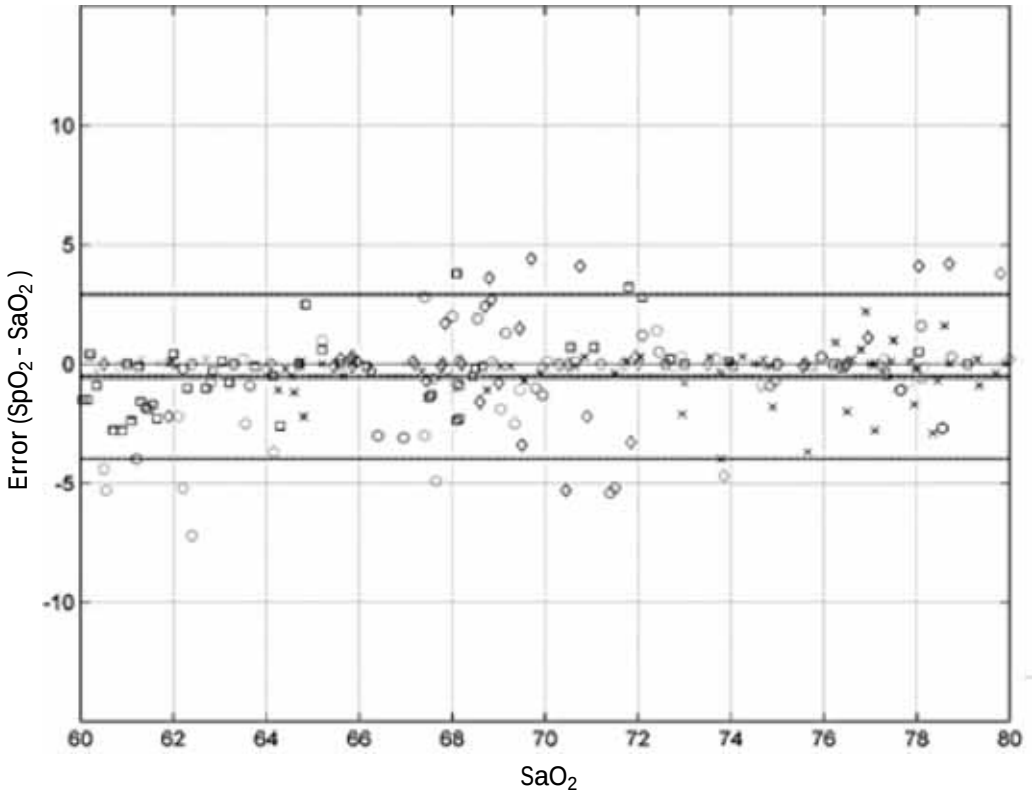
Rainbow Adhesive and Resposable Sensors, measured values	
Range	Arms
90-100%	1.25%
80-90%	1.45%
70-80%	1.94%



Rainbow DCI and DCIP Sensors

The table below shows Arms (Accuracy Root Mean Square) values measured using the rainbow DCI and DCIP sensors with Masimo SET Oximetry Technology in a clinical study. For accuracy in the range of 70% - 100% please see "M-LNCS/ LNCS/LNOP DCI and DCIP" on page D-12.

Rainbow DCI and DCIP, measured values	
Range	Arms
75-80%	1.56%
70-75%	1.67%
65-70%	1.86%
60-65%	2.13%

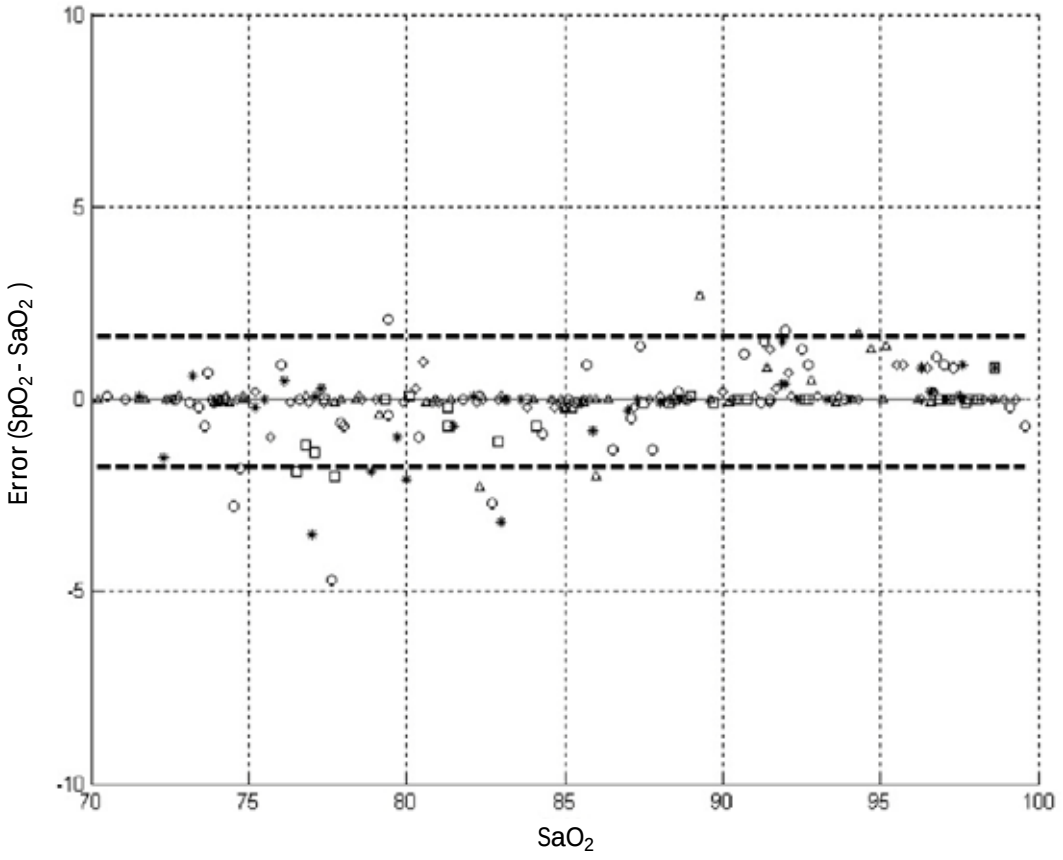


Performance Specifications for Masimo Sensors SpO_2 Multisite Reusable Sensors

The table below shows Arms (Accuracy Root Mean Square) values measured using the M-LNCS™/LNCS®/LNOP® Multisite sensors with Masimo SET Oximetry Technology in a clinical study.

M-LNCS™/LNCS®/LNOP® Series

M-LNCS™/LNCS®/LNOP® Multisite, measured values	
Range	Arms
90-100%	0.63%
80-90%	0.85%
70-80%	1.04%

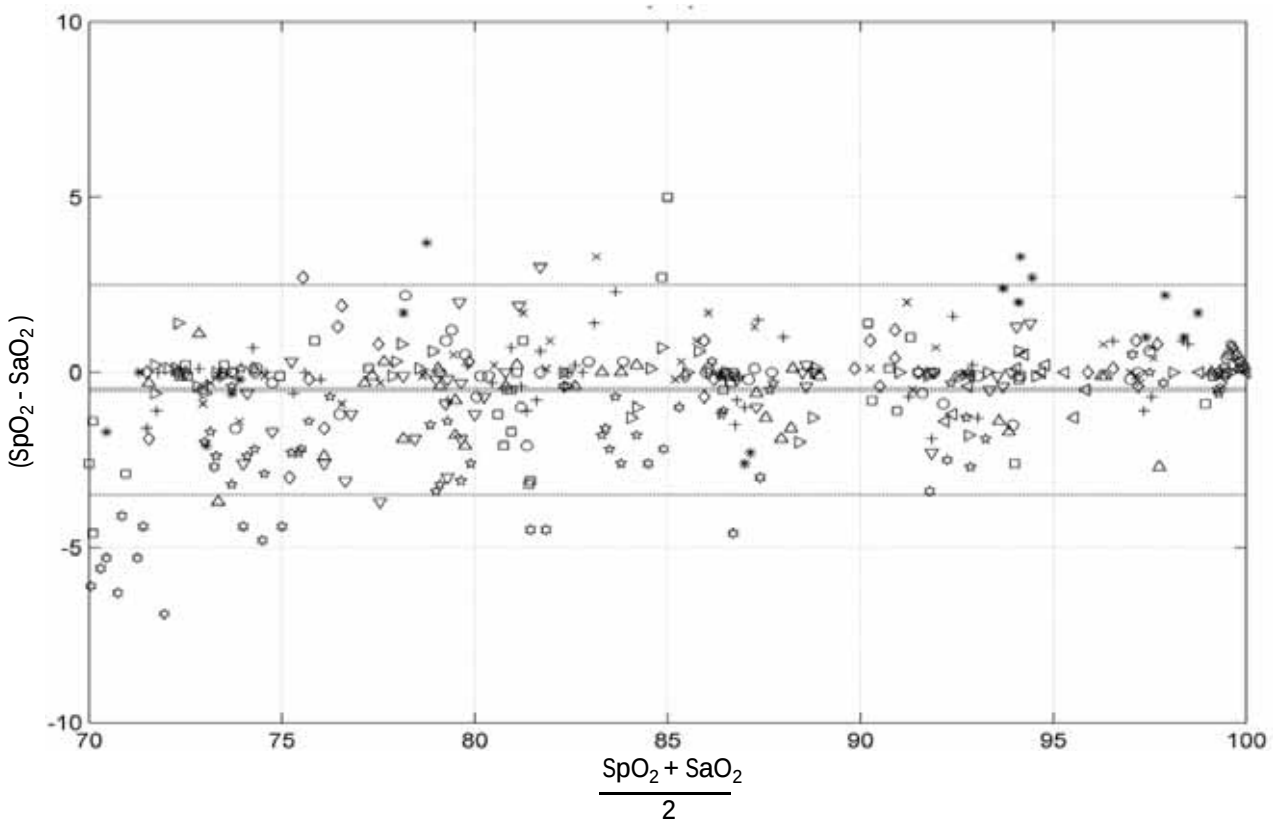


Performance Specifications for DBI™ Series

DBI Sensors with Masimo SET Oximetry Technology

The table below shows Arms (Accuracy Root Mean Square) values measured using the DBI reusable sensor with Masimo SET Oximetry Technology in a clinical study.

DBI Sensors with Masimo SET Oximetry Technology, measured values	
Range	Arms
90-100%	1.01%
80-90%	1.54%
70-80%	2.06%



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